



Suche in Studienregistern

Ablauf und Dokumentation

Vortragende: Elke Hausner

Workshop zur systematischen Literaturrecherche

Freiburg, 13.03.2018



Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

- Im Zuge des GKV-Modernisierungsgesetzes 2004 gegründet, Sitz in Köln
- Aufgabengebiet: Vor- und Nachteile medizinischer Leistungen für Patientinnen und Patienten objektiv zu überprüfen

Das Institut erstellt *unabhängige, evidenzbasierte Gutachten* beispielsweise zu:

- Arzneimitteln
- Nichtmedikamentösen Behandlungsmethoden (z.B. Operationsmethoden)

- HTA-Berichte „ThemenCheck Medizin“



ThemenCheck
Medizin

- Gesundheitsinformationen

gi gesundheitsinformation.de
verstehen | abwägen | entscheiden

Stabsbereich Informationsmanagement (S-IM) des IQWiG

- Besteht aus 6 wissenschaftlichen Mitarbeiter/innen (Recherche)
- Verantwortlich für die Informationsbeschaffung des Instituts
 - Auswahl der Suchquellen (z.B. Bibliografische Datenbanken, Studienregister)
 - Entwicklung, Qualitätssicherung und Durchführung von Suchstrategien
 - Prüfung und Bewertung der Informationsbeschaffung
- Technische Begleitung des Screeningprozesses: webTSDB
- Methodische Weiterentwicklung

Ablauf der Präsentation

- **Einführung ins Thema**
- Ablauf und Dokumentation der Suche in Studienregister

Suchquellen für die Erstellung systematischer Übersichten

- Suche nach publizierten Studien
 - Bibliografische Datenbanken (Medline, Embase etc.)
 - Primärstudien
 - Übersichtsarbeiten (Sichtung von Referenzlisten)
- Suche nach unpublizierten Studien
 - Anfragen an Hersteller, Studiengruppen und Fachgesellschaften
 - Öffentlich zugängliche Studienregister

→ Ziel: Minimierung von Bias^{1,2}

¹ Song F et al. Health Technol Assess. 2010; 14(8): iii-xi, 1-220.

² Schmucker C et al. PLoS ONE. 2014; 9(12): e114023.

Welche Daten können über die Suche gefunden werden?

- Durch die Suche in Studienregistern können Informationen gewonnen werden über^{1,2}:
 - die Existenz einer Studie,
 - Angaben zum Studiendesign und weiteren Informationen, wie Endpunkte und unerwünschte Ereignisse
 - bestimmte (Teil-)Ergebnisse einer Studie; Link zur Publikation der Studie
- hinterlegte Synopsen von Studienberichten sind z.T. ausführlicher als die Publikation selbst

¹ Wieseler B et al. BMJ 2012; 344: d8141.

² Zarin DA et al. N Engl J Med 2017; 376(4): 383-391.

Besonderer Stellenwert von Studienregistern

- International Committee of Medical Journal Editors (ICMJE) hat 2004 festgelegt, nur noch **klinische Studien** in ihren Fachzeitschriften zur Veröffentlichung zu akzeptieren, die vorab registriert wurden¹
- Gesetzliche Regelungen in den USA und Europa (**überwiegend AM-Studien**)
 - zur Registrierung von Studien, sowie
 - zur Veröffentlichung von Studienergebnissen

→ Bei nichtmedikamentösen Verfahren ist Studienregistrierung jedoch nicht sehr verbreitet: Publizierte Studien zur diagnostischen und prognostischen Güte hatten nur in **15%** einen zugehörigen Registereintrag²

¹ Huser V et al. J Am Med Inform Assoc 2013; 20(e1): e169-174.

² Korevaar DA. BMJ Open 2014; 4(1): e004596.

Was sind Studienregister?

Register, mit Angaben zum Studienprotokoll (**prospektiv**):

- Angaben zum Design geplanter Studien

Ergebnisregister (**nach Durchführung der Studie**):

- Ergebnisse abgeschlossener Studien

- In den letzten Jahren verschwimmen die Grenzen (siehe [ClinicalTrials.gov](https://www.clinicaltrials.gov))

Beispiele für Studienregister

Nationale Studienregister	<ul style="list-style-type: none"> • ClinicalTrials.gov • Deutsches Register Klinischer Studien (DRKS) • Nederlands Trial Register (NTR) • Australian New Zealand Clinical Trials Registry
Behördenregister	<ul style="list-style-type: none"> • EU-CTR (Europa) • PharmNet.Bund – Klinische Prüfungen (deutsch)
Firmenregister	<ul style="list-style-type: none"> • GlaxoSmithKline (GSK) Clinical Study Register • Forest Clinical Trial Registry
Krankheitsspezifische Studienregister	<ul style="list-style-type: none"> • ALOIS: a comprehensive register of dementia studies • Prospective Clinical Trials in the EBMT
Metaregister	<ul style="list-style-type: none"> • ICTRP Search Portal der WHO

Ablauf der Präsentation

- Einführung ins Thema
- **Ablauf und Dokumentation der Suche in Studienregistern**

Ablauf und Dokumentation der Suche in Studienregistern

- Wichtige Studienregister
 - Suche in den einzelnen Studienregistern
 - Screeningprozess
 - Dokumentation
 - Interne Dokumentation
 - Dokumentation in Berichten
- } Übung heute Nachmittag

Beispiel: Fingolimod bei Multipler Sklerose

WICHTIGE STUDIENREGISTER

Wichtige Studienregister

- ClinicalTrials.gov
- ICTRP Search Portal der WHO

-
- EU Clinical Trials Register (EU-CTR)  Arzneimittel



Allgemeine Infos: ClinicalTrials.gov

- US-amerikanisches nationales Studienregister
- Food and Drug Administration Amendments Act (**FDAAA**) **aus 2007**
 - Registrierung nahezu aller klinischen Studien (zu Medikamenten, biologischen Präparaten und Medizinprodukten), die in den Regulierungsbereich der FDA fallen
 - sowie die Hinterlegung der Studienergebnisse (innerhalb 12 Monate bzw. 30 Tage nach Zulassung)
- Momentan über **266.043 Einträge** aus **191 Ländern** hinterlegt, **30.023 Einträge** mit Studienergebnissen
- **NEU Final Rule 2016**
 - Klarstellung und Erweiterung des FDAAA z. B. werden nun auch von Studienergebnisse nicht zugelassener Produkte sowie Studienprotokolle veröffentlicht



Allgemeine Infos - ICTRP Search Portal

- Metaregister der WHO
 - Studienregister verschiedener Länder übermitteln Daten
- Seit 2007 online
- Momentan sind **323,547 Studien** zu recherchieren
- Umfasst:
 - **17 (nationale) Studienregister**, darunter auch das DRKS
 - Auch Studien aus ClinicalTrials.gov und dem EU-CTR enthalten

NEU: Sammelt bisher nur Registrierungsdaten, aber keine Ergebnisse (ab Mitte 2017)

(Stand: März 2018)



Allgemeine Infos: EU-CTR

- Studienregister der European Medicines Agency (EMA)
- Öffentlich zugänglicher Teil von EudraCT
- Art. 57 der Verordnung (EG) Nr. 726/2004
 - Erstellung einer der Öffentlichkeit zugänglichen Datenbank
 - Seit 2011 unter der Benennung **EU Clinical Trials Register (EU-CTR)** online
- Registrierung von Arzneimittelstudien der Europäischen Union sowie des Europäischen Wirtschaftsraums (EWR)
- Umfasst Phase II – IV Studien an Erwachsenen sowie klinische Studien an Kindern
- Momentan sind **31.983 Studien** zu recherchieren (+ **18.700 pädiatrische Studien**), **9.733 Einträge** mit Studienergebnissen

(Stand: März 2017)

SUCHE IN DEN EINZELNEN STUDIENREGISTERN

Suche in den einzelnen Studienregistern

Grundsätze beschrieben in:

Glanville, J. Journal of the Medical Library Association. 2014, 102(3): 177-183.

CT.gov und **ICTRP**:

Suchanfragen sollten umfassen:

- mehrere Suchbegriffe
- nur ein Konzept (Indikation oder Intervention)

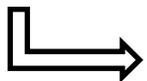
Suche in den einzelnen Studienregistern

Suche nach neuen Arzneimitteln

IQWiG. Suchen in Studienregistern nach Studien zu neu zugelassenen Arzneimitteln:
Arbeitspapier.

CT.gov: Suche mit einzelnen Begriffen (Wirkstoffname, plausibel abgeleiteter Begriff zur Indikation) erzielen sensitive Ergebnisse

ICTRP und **EU-CTR:** Mehrere Suchbegriffe (wirkstoffbezogene Suche: neben Wirkstoffnamen entsprechender Wirkstoffcode; indikationsbezogene Suche: textanalytisch abgeleitete Begriffe) notwendig, um sensitive Ergebnisse zu erzielen



wenn möglich Suche zu einem Konzept

Suche in den einzelnen Studienregistern

Suche nach neuen Arzneimitteln

	Indikation	Arzneimittel
CT.gov	Multiple sclerosis	Fingolimod
ICTRP	multiple sclerosis, ms	Fingolimod, FTY 720
EU CTR	multiple sclerosis, ms	Fingolimod, FTY 720

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

NEU

ClinicalTrials.gov BETA

A service of the U.S. National Institutes of Health

[Leave beta test site](#)

Saved Studies (0)

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 [Submit Studies](#) ▾ |
 [Resources](#) ▾ |
 [About Site](#) ▾

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

IMPORTANT: Information on ClinicalTrials.gov is provided by the sponsor or principal investigator of the clinical study, and posting to this site does not necessarily reflect endorsement by NIH. ClinicalTrials.gov does not independently verify the scientific validity or relevance of the submitted information beyond a limited quality control review for apparent errors, deficiencies, or inconsistencies. **Talk with a trusted healthcare professional before choosing to participate in a clinical study.**

Search

Condition / Disease:

Intervention / Treatment:

Other Terms:

Location: US State:

Country:

The database currently lists **239,638 studies** with locations in all 50 States and in **197 countries**.

Recruiting Study Locations

Non-U.S. only	56%
U.S. only	39%
Both U.S. and non-U.S.	5%

41,502 recruiting studies (March 22, 2017)

[Final Rule Webinar Series](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

Patients and Families

Search for actively recruiting studies that you may be able to participate in or learn about new treatments that are being considered.

[Learn more](#)

Researchers

Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

[Learn more](#)

Study Record Managers

Learn about registering studies and about submitting their results after study completion.

[Learn more](#)

Suchoberfläche – Advanced Search

Advanced Search

Fill in any or all of the fields below. Click on the label to the left of each search field for more information or read the [Help](#)

[Help](#)

Search Terms:

Study Type: All Studies

Study Results: All Studies

Study Status: **Studies:**

- Not yet recruiting
- Recruiting
- Recruiting by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status

Expanded Access:

- Available
- No longer available
- Temporarily not available
- Approved for marketing

- Entspricht „Other Terms“,
- Durchsucht die wichtigen Felder des Datensatzes



Suchfunktionalitäten

- Phrasensuche: "heart attack"
- Boolesche Operatoren
 - Eingabe in Großbuchstaben: AND, OR, NOT
 - Verwendung von Klammern zur Strukturierung der Suche möglich
 - (heart disease OR heart attack) AND (stroke OR clot)
- Trunkierung
 - Wird in der "Hilfe" nicht beschrieben → nicht verwenden!

Weitere Informationen: <http://clinicaltrials.gov/ct2/help/help>

Suchoberfläche – Advanced Search

Advanced Search

Fill in any or all of the fields below. Click on the label to the left of each search field for more information or read the [Help](#)

[Help](#)

Search Terms:

Study Type:

Study Results:

Study Status: **Studies:**

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
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Expanded Access:

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- No longer available
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Ergebnisdarstellung

List By Topic On Map **Search Details**

Recognized Terms and Synonyms:

Fingolimod: 86 studies

Gilenya: 34 studies

FTY 720: 45 studies

Multiple sclerosis: 1594 studies

- Disseminated sclerosis
- MS gene
- Multiple sclerosis
- insular sclerosis

sclerosis: 2337 studies

- Sclerotic
- hardening of the tissue
- sclerose

Multiple: 40871 studies

- Many
- Multi
- Numerous
- Plural
- Several

[How to Use Search Results](#) | [Glossary](#)

67 Studies found

Study Title	Conditions	Interventions
...bility of Fingolimod in Patients With ...g Multiple Sclerosis	Multiple Sclerosis	Drug: Fingolimod
...mized, Open-label, Patient ...and Tolerability Study of ...20) 0.5 mg/Day vs. Comparator in ...psing Forms of Multiple Sclerosis	Relapsing Forms of Multiple Sclerosis	Drug: Fingolimod; Drug: Standard MS DMTs
...y of Fingolimod (FTY720) in	Multiple Sclerosis	Drug: Fingolimod; Drug: Placebo

Ergebnisdarstellung – Studienergebnisse

67 Studies found

List By Topic On Map Search Details

Download Subscribe to RSS

Show/Hide Columns

Showing: 1-10 of 67 studies 10 studies per page

Filters

Apply Clear

Status

Studies:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status*

Expanded Access:

- Available
- No longer available
- Temporarily not available
- Approved for marketing

Rank	Saved	Status	Study Title	Conditions	Interventions
1	<input type="checkbox"/>	Completed Has Results	Safety and Tolerability of Fingolimod in Patients With Relapsing-remitting Multiple Sclerosis	Multiple Sclerosis	Drug: Fingolimod
2	<input type="checkbox"/>	Completed Has Results	A 6-month, Randomized, Open-label, Patient Outcomes, Safety and Tolerability Study of Fingolimod (FTY720) 0.5 mg/Day vs. Comparator in Patients With Relapsing Forms of Multiple Sclerosis	Relapsing Forms of Multiple Sclerosis	Drug: Fingolimod; Drug: Standard MS DMTs
3	<input type="checkbox"/>	Completed Has Results	Efficacy and Safety of Fingolimod (FTY720) in Patients With Relapsing-remitting Multiple Sclerosis	Multiple Sclerosis	Drug: Fingolimod; Drug: Placebo
4	<input type="checkbox"/>	Completed Has Results	An Extension Study of the Efficacy and Safety of Fingolimod (FTY720) in Patients With Relapsing Multiple Sclerosis	Multiple Sclerosis	Drug: Fingolimod
5	<input type="checkbox"/>	Completed Has Results	Long-term Efficacy and Safety of Fingolimod (FTY720) in Patients With Relapsing-remitting Multiple Sclerosis	Multiple Sclerosis	Drug: Fingolimod 0.5 mg; Drug: Fingolimod 1.25 mg
6	<input type="checkbox"/>	Completed	Evaluating the Effect of Fingolimod With Fish Oil	Multiple Sclerosis	Drug: Fingolimod; Dietary Supplement: Fish Oil; Drug: Placebo (for Fish Oil)

NEU: direkte Filterung der Ergebnisse nach Study Status, Study Type usw möglich



Studienergebnisse

Trial record **1 of 67** for: Fingolimod AND Multiple sclerosis

[Previous Study](#) | [Return to List](#) | [Next Study](#) ▶

Safety and Tolerability of Fingolimod in Patients With Relapsing-remitting Multiple Sclerosis

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01497262

First received: December 5, 2011
Last updated: March 17, 2015
Last verified: March 2015
[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[Study Results](#)

[Disclaimer](#)

[? How to Read a Study Record](#)

▶ Purpose

This 4 month, open-label study will evaluate the safety and tolerability of **fingolimod** 0.5 mg in patients with relapsing-remitting **multiple sclerosis** (RRMS) and generate additional data in **Multiple Sclerosis** (MS) patient population that closely resembles the clinical population seen in routine medical care.

Condition	Intervention	Phase
Multiple Sclerosis	Drug: Fingolimod	Phase 3



Export der Referenzen

67 Studies found

List By Topic On Map Search Details

Hide Filters

Filters

Apply Clear

Status

Studies:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status

Expanded Access:

- Available
- No longer available
- Temporarily not available
- Approved for marketing

Showing: 1-10 of 67 studies

Rank	Saved	Status	Conditions	Interventions
1	<input type="checkbox"/>	Completed Has Results		Drug: Fingolimod
2	<input type="checkbox"/>	Completed Has Results	of Multiple Sclerosis	Drug: Fingolimod; Drug: Standard MS DMTs
3	<input type="checkbox"/>	Completed Has Results		Drug: Fingolimod; Drug: Placebo
4	<input type="checkbox"/>	Completed Has Results	An Extension Study of the Efficacy and Safety of Fingolimod (FTY720) in Patients With Relapsing Multiple Sclerosis	Multiple Sclerosis Drug: Fingolimod
5	<input type="checkbox"/>	Completed Has Results	Long-term Efficacy and Safety of Fingolimod (FTY720) in Patients With Relapsing-remitting Multiple Sclerosis	Multiple Sclerosis Drug: Fingolimod 0.5 mg; Drug: Fingolimod 1.25 mg
6	<input type="checkbox"/>	Completed	Evaluating the Effect of Fingolimod With Fish Oil on Relapsing-Remitting Multiple Sclerosis Patients	Multiple Sclerosis Drug: Fingolimod; Dietary Supplement: Fish Oil; Drug: Placebo (for Fish Oil)

Download

Subscribe to RSS

Show/Hide Columns

Download the search results for:
Fingolimod AND Multiple sclerosis (67 records)

Need help? See [Downloading Content for Analysis](#)

Number of Studies:

Download Content:

Download All Study Fields as XML
 Download All Study and Results Fields as XML
 Download Selected Fields:

Select fields:

Select file format:

zip file readers with free trial periods: WinZip and PKZip



Home **Advanced Search** List By Search Tips UTN ICTRP website Contact us

Example: liver cancer OR breast cancer NOT genetic [Search tips](#)

- **Abgeschlossene und laufende Studien**
- **Suche in mehreren Feldern: u.a. Title, Condition, Intervention**

Phase 1
Phase 2
Phase 3
Phase 4

Welcome

- The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records.
- To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. [More information](#)
- Please note: This Search Portal is not a clinical trials registry. [How to register a trial](#)
- For mobile users, please use this link <http://apps.who.int/trialsearch/ictrpmob.aspx>. It can be opened from any smartphone
- It is now possible to export the results of the search into XML. [More information](#)
- Crawling the ICTRP database now requires a username/password. To request access to the crawling pages please send an email to ictrpinfo@who.int (This service is now enabled)
- A new field called 'Prospective registration' has been added to the ICTRP database, More details about this new field can be found [here](#)

Data Providers

Data sets from [data providers](#) are updated every Wednesday evening according to the following schedule:
Every week:

- Australian New Zealand Clinical Trials Registry, last data file imported on **21 March 2017**
- Chinese Clinical Trial Registry, last data file imported on **21 March 2017**
- ClinicalTrials.gov, last data file imported on **21 March 2017**
- EU Clinical Trials Register (EU-CTR), last data file imported on **21 March 2017**
- ISRCTN, last data file imported on **21 March 2017**
- The Netherlands National Trial Register, last data file imported on **21 March 2017**

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on **13 March 2017**
- Clinical Trials Registry - India, last data file imported on **13 March 2017**
- Clinical Research Information Service - Republic of Korea, last data file imported on **27 February 2017**
- Cuban Public Registry of Clinical Trials, last data file imported on **27 February 2017**
- German Clinical Trials Register, last data file imported on **27 February 2017**
- Iranian Registry of Clinical Trials, last data file imported on **28 February 2017**
- Japan Primary Registries Network, last data file imported on **27 February 2017**
- Pan African Clinical Trial Registry, last data file imported on **27 February 2017**
- Sri Lanka Clinical Trials Registry, last data file imported on **27 February 2017**
- Thai Clinical Trials Register (TCTR), last data file imported on **13 March 2017**
- ****New**** Peruvian Clinical Trials Registry (REPEC), last data file imported on **14 March 2017**



Suchoberfläche – Advanced Search

Home **Advanced Search** List By Search Tips UTN ICTRP website Contact us

Fields can be left blank. Click on the field name hyperlink for an explanation of each search field

Look for trials with the exact phrase or contains

Example: liver cancer OR breast cancer in the [Title](#)

AND Example: Diphtheria NOT tetanus in the [Condition](#)

AND Example: transplant AND immunosuppressant in the [Intervention](#)

Search for [clinical trials in children](#)

[Recruitment status](#) is

[Primary sponsor](#) is or contains

[Secondary ID](#) is or contains

[Countries of recruitment](#) are

Free Text Country :

[Date of registration](#) is between and

[Phases](#) are



Suchfunktionalitäten

- Phrasensuche
 - 2 oder mehrere Wörter werden automatisch als Phrase gesucht
 - Anführungszeichen sollen nicht verwendet werden
- Boolesche Operatoren
 - Klammern können nicht verwendet werden, um eine Suche zu strukturieren
 - Hierarchische Anwendung 1. NOT, 2. AND, 3. OR
 - Das geht nicht: **heart attack AND (aspirin OR clopidogrel)**
 - Richtig: **heart attack AND aspirin OR heart attack AND clopidogrel**
- Trunkierung (*)
 - Trunkierung nicht in der Mitte eines Worter oder einer Phrase verwenden → **heart* attack** (erzielt keine / falsche Treffer)
 - Trunkierung deaktiviert die Synonymsuche! → **unklar**

Suchoberfläche – Standard Search

A screenshot of the WHO ICTRP Search Portal interface. The top header is blue with the WHO logo and "World Health Organization" text. Below it is the ICTRP logo and "International Clinical Trials Registry Platform Search Portal" text. A navigation bar contains links: Home, Advanced Search, List By, Search Tips, UTN, ICTRP website, and Cor. A search input field is highlighted with a red border and contains the text "Fingolimod OR FTY 720 OR FTY720". To the right of the input field is a "Search" button and a "Search tips" link.

World Health Organization

International Clinical Trials Registry Platform Search Portal

Home Advanced Search List By Search Tips UTN ICTRP website Cor

Fingolimod OR FTY 720 OR FTY720 Search [Search tips](#)



Ergebnisdarstellung

World Health Organization

International Clinical Trials Registry Platform Search Portal

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Back to Search

Export to CSV
Export results to XML

269 records for 109 trials found for: Fingolimod OR FTY 720 OR FTY720 [\(What is this?\)](#)
Show 10 records per page

Recruitment status	Prospective Registration	Main ID	Public Title	Date of Registration
Not recruiting	No	NCT02939079	Evaluating of the Effect of Fingolimod With Fish Oil on Relapsing-Remitting Multiple Sclerosis Patients	14/10/2016
Not recruiting	Yes	NCT02956200	Combinating Fingolimod With Alteplase Bridging With Mechanical Thrombectomy in Acute Ischemic Stroke	11/10/2016
Not recruiting	No	NCT02799199	Fingolimod Real World Experience: the French Grand-Est Cohort	27/05/2016
Recruiting	Yes	NCT02720107	Follow up Study of Patients on Fingolimod Who Were Enrolled in the Original Biobank Study (CFTY720DDE01)	21/03/2016
Recruiting	Yes	NCT02769689	Methylprednisolone During the Switch Between Natalizumab and Fingolimod	17/03/2016
Recruiting	Yes	IRCT201407018323N11	The evaluation of the Effect of Fingolimod on Fatigue and depression in patients with M.S	2016-01-23
Not recruiting	Yes	NCT02632591	Use on Human Beings of Mix of Known Drugs for New Destination - MS Treatment	14/12/2015
Recruiting	Yes	NCT02575365	Effect of Fingolimod on Neurodegeneration	12/10/2015
Not recruiting	Yes	ACTRN12615001055594	Comparative bioequivalence study of a generic formulation of fingolimod capsule against the innovator fingolimod capsule in fasting healthy subjects	07/10/2015
Recruiting	Yes	NCT02490930	A Safety Study of Fingolimod With Radiation and Temozolomide in Newly Diagnosed High Grade Glioma	02/07/2015



EU Clinical Trials Register

Help

Home & Search

Joining a trial

Contacts

About

Clinical trials

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn [more about the EU Clinical Trials Register](#) including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays **30014** clinical trials with a EudraCT protocol, of which **4604** are clinical trials conducted with subjects less than 18 years old.

The register also displays information on **18700** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).



Search

Examples: Cancer AND drug name. Pneumonia AND sponsor name.

[How to search \[pdf\]](#)

Advanced Search: [Search tools](#)



Suchfunktionalitäten (z. B. nicht auf Website beschrieben)

- Phrasensuche: "heart attack"
 - Achtung: Synonymsuche wird deaktiviert
- Boolesche Operatoren
 - Eingabe in Großbuchstaben: AND, OR, NOT
 - Verwendung von Klammern zur Strukturierung der Suche möglich
- Trunkierung
 - Wird in der "Hilfe" nicht beschrieben → ist jedoch möglich
 - ? für genau ein Zeichen, * für 0 oder beliebig viele Zeichen

Weitere Informationen: https://www.clinicaltrialsregister.eu/doc/How_to_Search_EU_CTR.pdf



ACHTUNG: Nicht transparente Verarbeitung von zusammengesetzten Begriffen

- fingolimod OR fty720 OR "fty 720" → 48 Treffer
- fingolimod OR fty720 OR (fty 720) → 48 Treffer

jedoch

- fingolimod OR fty720 OR **fty 720** → 185 Treffer
- **fty 720** OR fingolimod OR fty720 → 1 Treffer



Suchoberfläche

EU Clinical Trials Register Help

[Home & Search](#) [Joining a trial](#) [Contacts](#) [About](#)

Clinical trials for fingolimod OR fty720 OR (fty 720)

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Examples: Cancer AND drug name, Pneumonia AND sponsor name

[How to search \[pdf\]](#)

Advanced Search: [Search tools](#)



Ergebnisdarstellung

Trials with a EudraCT protocol (47)

Paediatric studies in scope of Art45 of the Paediatric Regulation (0)

47 result(s) found for: fingolimod OR fty720 OR (fty 720). Displaying page 1 of 3.

1 2 3 Next»

EudraCT Number: 2014-001241-24	Sponsor Protocol Number: CFTY720D2409	Start Date * : 2014-07-30
Sponsor Name: Novartis Pharma Service AG		
Full Title: Long-term, open-label, multicenter study assessing long-term cardiovascular risks in patients treated with fingolimod		
Medical condition: Cardiovascular risk		
Disease:		
Population Age: Adults, Elderly	Gender: Male, Female	
Trial protocol: BE (Ongoing)		
Trial results: (No results available)		

EudraCT Number: 2011-004160-30	Sponsor Protocol Number: CFTY720D2205	Start Date * : 2013-05-08			
Sponsor Name: Novartis Pharma Service AG					
Full Title: A multicenter, randomized, active-controlled study to assess the safety, tolerability, and efficacy of FTY720 in patients with acute, noninfectious intermediate, posterior and pan uveitis					
Medical condition: Uveitis, intermediate; uveitis, posterior; uveitis, pan.					
Disease:	Version	SOC Term	Classification Code	Term	Level
	14.1	10015919 - Eye disorders	10046851	Uveitis	PT
Population Age: Adults			Gender: Male, Female		

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Summary Details

Download Format:
Plain Text

Note, where multi-state trials are shown in search results, selecting "Full Trial details" will download full information for each of the member states/countries involved in the trial.

Summary

EudraCT Number:	2014-001241-24
Sponsor's Protocol Code Number:	CFTY720D2409
National Competent Authority:	Belgium - FPS Health-DGM
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2014-07-07
Trial results	

Index

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- [B. SPONSOR INFORMATION](#)
- [C. APPLICANT IDENTIFICATION](#)
- [D. IMP IDENTIFICATION](#)
- [D.8 INFORMATION ON PLACEBO](#)
- [E. GENERAL INFORMATION ON THE TRIAL](#)
- [F. POPULATION OF TRIAL SUBJECTS](#)
- [G. INVESTIGATOR NETWORKS TO BE INVOLVED IN THE TRIAL](#)
- [N. REVIEW BY THE COMPETENT AUTHORITY OR ETHICS COMMITTEE IN THE COUNTRY CONCERNED](#)
- [P. END OF TRIAL](#)

[Expand All](#)

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A. Protocol Information ⌵ ⌴

A.1	Member State Concerned	Belgium - FPS Health-DGM
A.2	EudraCT number	2014-001241-24
A.3	Full title of the trial	Long-term, open-label, multicenter study assessing long-term cardiovascular risks in patients treated with fingolimod

 **EU Clinical Trials Register**

Export

Trials with a EudraCT protocol (47)

Paediatric studies in scope of Art45 of the Paediatric Regulation (0)

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1 2 3 Next»

EudraCT Number: 2014-001241-24 **Sponsor Protocol Number:** CFTY720D2409 **Start Date** * : 2014-07-30

Sponsor Name: Novartis Pharma Service AG

Full Title: Long-term, open-label, multicenter study assessing long-term cardiovascular risks in patients treated with fingolimod

Medical condition: Cardiovascular risk

Disease:

Population Age: Adults, Elderly **Gender:** Male, Female

Trial protocol: [BE](#) (Ongoing)

Trial results: (No results available)

EudraCT Number: 2011-004160-30 **Sponsor Protocol Number:** CFTY720D2205 **Start Date** * : 2013-05-08

Sponsor Name: Novartis Pharma Service AG

Full Title: A multicenter, randomized, active-controlled study to assess the safety, tolerability, and efficacy of FTY720 in patients with acute, noninfectious intermediate, posterior and pan uveitis

Medical condition: Uveitis, intermediate; uveitis, posterior; uveitis, pan.

Disease:	Version	SOC Term	Classification Code	Term	Level
	14.1	10015919 - Eye disorders	10046851	Uveitis	PT

Population Age: Adults **Gender:** Male, Female

Subscribe to this Search

To subscribe to the RSS feed for this search click [here](#) . This will provide an RSS feed for clinical trials matching your search that have been added or updated in the last 7 days.

Download Options:

Number of Trials to download:

Download Content:

Download Format:

Note, where multi-state trials are shown in search results, selecting "Full Trial details" will download full information for each of the member states/countries involved in the trial.

Tipps zur Suche in Studienregistern

ClinicalTrials.gov

heart at	heart attack*	OR clopidogrel)
----------	---------------	-----------------

18783 studies found for: heart NOT attack

- **Kenne die Suchfunktionalitäten der Studienregister**
 - Boolesche Operationen: Großschreibung beachten!
 - Verwendung von Klammern
 - Trunkierung
- **Durchsuche die wichtigen Studienregister direkt**
 - ClinicalTrials.gov
 - EU-CTR
- **KEEP IT SIMPLE!**
 - Keine Verknüpfung von Suchzeilen möglich
 - Hinterlegte Synonymsuche in Überlegungen einbeziehen
 - Komplexe Suchanfragen erzeugen Fehlermeldungen oder Fehler

Ablauf und Dokumentation der Suche in Studienregister

- Auswahl der Studienregister
- Suche in den einzelnen Studienregistern
- **Screeningprozess**
- Dokumentation
 - Interne Dokumentation
 - Dokumentation in Berichten

Suche und Export in Excel ist erfolgt – was dann?

A	B	C	D	E	F	G	H
1	NCT012597	Title	Recruitment	Study Results	Conditions	Interventions	Sponsor
2	NCT0218196	Bupropion SR for Major Depression and Dry Terminated	Not recruiting	No Results Available	Depression (Major Depres Drug; bupropion		Novartis
3	NCT0202919	Paroxetine/Bupropion in Suicide Attempts/Completed		No Results Available	Depression (Bipolar Disor Drug; bupropion SR		Massachusetts
4	NCT0234135	Wellbutrin XL, Major Depressive Disorder/Completed		No Results Available	Depression Drug; Paroxetine CR for National Inst		
5	NCT0217244	Risperidone vs. Bupropion ER Augmentation/Completed		No Results Available	Breast Cancer (Major Dep Drug; bupropion exten		Thomas Jefferson
6	NCT0204252	A Study of Nefopam SR/Bupropion SR in/Completed		No Results Available	Unipolar Depression Drug; Risperidone (drug)		Vanderbilt Un
7	NCT0209722	Are Two Antidepressants a Good Initial Tr/Completed		No Results Available	Depression Drug; bupropion SR 12 (Chengun Th		
8	NCT0202182	Major Depressive Disorder in The Elderly /Completed		No Results Available	Major Depressive Disordr Drug; Escitalopram (Drug New York St		Glastronitha
9	NCT0205617	Study in Patients With Depression Not Res/Completed		Has Results	Major Depressive Disordr Drug; Placebo (Drug 323 GlasstrinH		
10	NCT0049027	Fluoxetine and Bupropion to Treat Patients/Active, not recruiting		No Results Available	Depression (Alcoholism) Drug; Fluoxetine (Drug 4 National Inst		
11	NCT0001483	Acute Effectiveness of Additional Drugs to/Completed		No Results Available	Bipolar Disorder (Depress Drug; bupropion (SR) National Inst		
12	NCT0202525	Wellbutrin XL for Dysthymic Disorder /Completed		No Results Available	Dysthymic Disorder Drug; bupropion XL 50 (Luker-Ro		
13	NCT0203942	Study Of Bupropion SR (323)66 SR in Patients/Completed		Has Results	Major Depressive Disordr Drug; 32366 SR		Glastronitha
14	NCT0205834	Bupropion For Reducing High-Risk Behavio/Active, not recruiting		No Results Available	HIV Infections (Depress Drug; Bupropion National Inst		
15	NCT0205835	Effect of Antidepressants on The Treatment/Drilling by Invitation		No Results Available	Major Depressive Disordr Drug; paroxetine (Drug; Ministry of H		
16	NCT0209933	Memory Functioning and Antidepressant T/Completed		No Results Available	Major Depressive Disordr Drug; Escitalopram (Drug University H		
17	NCT0091229	Effects of Antidepressants on Sexual Funct/Completed		No Results Available	Major Depressive Disordr Drug; Extended-release (Glastronitha		
18	NCT0204502	Wellbutrin XL Effects on SSRIs-induced Ch/Completed		No Results Available	Depression (Side Effects) Drug; Wellbutrin XL		Indava una
19	NCT0205828	Dynamic Measures of Neurochemistry in M/Active, not recruiting		No Results Available	Depression Drug; sertraline (Drug; In Vanderbilt Un		
20	NCT0151650	Sexual Functioning Study With Antidepress/Completed		No Results Available	Depressive Disorder; MAO Drug; Bupropion hydrochloride (Glastronitha		
21	NCT0303434	Effect of Ethanol and Genetic Polymorpho/Completed		No Results Available	Alcohol Drinking (Depress Drug; Bupropion (Drug C National Inst		
22	NCT0013532	Study Of 32366 SR in Major Depressive Dis/Completed		No Results Available	Major Depressive Disordr Drug; bupropion hydrochloride (Glastronitha		
23	NCT0202044	The Effects of Acute Administration of Bup/Completed		No Results Available	Major Depressive Disordr Drug; Bupropion (Drug) Effective vs		
24	NCT0004029	Seasonal Affective Depression (SAD) Study/Completed		No Results Available	Seasonal Affective Disordr Drug; Extended-release (Glastronitha		
25	NCT0004445	Litharge Depression Study/Completed		No Results Available	Major Depressive Disordr Drug; Extended-release (Glastronitha		
26	NCT0068935	Does Sleep Quality Change After Search in/Active, not recruiting		No Results Available	Mood Disorder Drug; Wellbutrin XL Queen Un		
27	NCT0061272	Effects of Antidepressants On Sexual Funct/Completed		No Results Available	Major Depressive Disordr Drug; Extended-release (Glastronitha		
28	NCT0070866	Combining Medications to Balance Depres/Completed		No Results Available	Major Depressive Disordr Drug; One of the Below National Inst		
29	NCT0004241	Prevention of Seasonal Affective Disorder /Completed		No Results Available	Seasonal Affective Disordr Drug; Extended-release (Glastronitha		
30	NCT0064816	A Retrospective Bioavailability Study of Bupropion/Completed		No Results Available	Depression Drug; Bupropion NCI SR (Sandwich Inc		

A	B	C	D
Recruitment status	Main ID	Public Title	Date of registration
Not recruiting	ISRCTN44468346	Assessment of Augmentation Strategies to Optimize the Therapeutic Response to Wellbutrin in Major Depression	15.02.2006
Recruiting	ISRCTN00111399	Are antidepressants more effective than placebo, when given in combination with mood stabilisers in preventing mood episodes in people with bipolar disorder?	26.11.2009
Not recruiting	NCT00001483	Acute Effectiveness of Additional Drugs to the Standard Treatment of Depression	03.11.1999
Not recruiting	NCT00051259	Effects of Antidepressants on Sexual Functioning	07.01.2005
Not recruiting	NCT00051272	Effects of Antidepressants On Sexual Functioning in Adults	07.01.2005
Not recruiting	NCT00057551	Research Evaluating the Value of Augmenting Medication With Psychotherapy, (BIVAMP)	04.04.2000
Not recruiting	NCT00064467	Lethargic Depression Study	08.07.2005
Not recruiting	NCT00009459	Seasonal Affective Depression (SAD) Study	25.09.2003
Not recruiting	NCT00080158	Treatment of Adolescent Suicide Attempts (TASA)	24.03.2004
Recruiting	NCT00106197	Hormone and Sleep Response to Antidepressant Treatment in Adolescents and Adults with Depression	21.03.2005
Not recruiting	NCT00125957	The Effects of Bupropion on Residual and Cognitive Symptoms in SSRIs-treated Depression	01.08.2005
Not recruiting	NCT00135512	Study Of 32366 SR in Major Depressive Disorder	24.08.2005
Not recruiting	NCT00178828	Dynamic Measures of Neurochemistry in Mood Disorders	12.09.2005
Not recruiting	NCT00179244	Depression vs. Bupropion SR Augmentation of SSRIs in Treatment-Resistant Depression	13.09.2005
Not recruiting	NCT00181896	Bupropion SR for Major Depression and Depression NOS in Children and Adolescents with Bipolar Disorder	13.09.2005
Not recruiting	NCT00186446	Treatment of Nicotine Dependence and Acute Depression	13.09.2005

D	E
Full Title:	Link:
arma Sei A 24-month Extension to a one-year, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
arma A two-year, double-blind, randomized, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A multicenter, randomized, active-controlled study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A 32-week, patient- and rater-blinded, randomized, multicenter study to	https://www.clinicaltrialsregister.eu/ct
arma Sei A 4-month, open-label, multi-center study to provide a	https://www.clinicaltrialsregister.eu/ct
arma AG A double-blind, randomized, placebo-controlled study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A single arm, open-label, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Gn A 6 months, randomized, multicenter, parallel study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A open-label, single-arm extension study to provide a	https://www.clinicaltrialsregister.eu/ct
FARMA S An open-label, single arm study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A 12-month double-blind, randomized, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A double-blind, randomized, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A 24-month double-blind, randomized, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
tsklinik A 32-week, monocentric, exploratory, single arm study to provide a	https://www.clinicaltrialsregister.eu/ct
FARMA A 6-month, randomized, Active Comparator study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Sei A 24-month double-blind, randomized, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
armaceut A 48-week, double-blind, randomized, multicenter study to provide a	https://www.clinicaltrialsregister.eu/ct
arma Gn A 1-week, open-label, multi-center study to provide a	https://www.clinicaltrialsregister.eu/ct

ClinicalTrials.gov
Screening

ICTRP Search Portal

EU-CTR

- Wird von 2 Personen unabhängig voneinander durchgeführt
- Links zu den Registereinträgen müssen beim Übertrag erhalten bleiben

Exportfilter

<http://community.cochrane.org/organizational-info/resources/resources-groups/information-specialists-portal/searching/clinical-trials>

Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness

Methodische Leitlinie

- Ablauf der Suche in Studienregistern
- Praxisbeispiel
- Stand Dezember 2017



http://eunethta.eu/sites/default/files/Guideline_Information_Retrieval_V1-2_2017.pdf

Weitere Informationen

YHEC Training Event: Trials Registers, Trials Results Registers and Other Research Registers, Organisatorin: Julie Glanville

Newsletter: <http://php.york.ac.uk/inst/yhec/?q=newsletter>

Glanville, J., et al. (2014). "Searching ClinicalTrials.gov and the International Clinical Trials Registry Platform to inform systematic reviews: what are the optimal search approaches?" *Journal of the Medical Library Association* **102**(3): 177-183.

Fachpublikation des IQWiG

Knellingen, M., et al. (2018). "Trial registry searches for randomized controlled trials of new drugs required registry-specific adaptation to achieve adequate sensitivity." *Journal of Clinical Epidemiology* **94**: 69-75.



Genereller Zugang zu Studienergebnissen

In Europa stehen im Bereich der AM-Zulassung weitreichende Änderungen an:

- EU-Verordnung (Nr. 536/2014): Gesetz zur Neufassung der Clinical Trials Regulation. Veröffentlichung aller Studienergebnisse der EU-Arzneimittelbehörde EMA.
- Veröffentlichungspflicht von Studienergebnissen innerhalb bestimmter Zeiträume (z.B. 12 Monate nach Ende der Studie)
- Pflicht zur Veröffentlichung von Informationen zu: Fragestellung, Design, Hauptergebnisse und Schlussfolgerung der Studie
- **Gekoppelt an die Entwicklung eines zentralen EU-Portals (noch nicht realisiert)**
- **Davon abzugrenzen:** „EMA Policy“ zur Veröffentlichung von Studienberichten nach Zulassungsentscheidung (gilt ab dem 1.1.2015).

NEU: EMA Policy 0070: Zugang zu Zulassungsdokumenten (einschließlich Studienberichten)

- EMA Clinical Data (<https://clinicaldata.ema.europa.eu>)
Stand: 15.02.2018: 73 Einträge

Es gibt 2 Zugriffsmöglichkeiten:

1. „Screen only“: dafür ist lediglich eine Registrierung notwendig
2. Zugriff mit Möglichkeit, die Dokumente herunterzuladen. (Voraussetzungen: Standort in der EU, umfangreichere Angaben wie Ausweisnummer)

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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- D-50670 Köln
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- Telefax +49-221/3 56 85-1
- info@iqwig.de
- www.iqwig.de



More Information

Go to 

Responsible Party: Eli Lilly and Company
ClinicalTrials.gov Identifier: [NCT03433677](#) [History of Changes](#)
Other Study ID Numbers: 16908
I8B-MC-ITSI (Other Identifier: Eli Lilly and Company)
2017-002374-39 (EudraCT Number)
First Posted: **February 14, 2018** [Key Record Dates](#)
Last Update Posted: February 14, 2018
Last Verified: February 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes

Plan Description: Lilly provides access to the individual patient data from studies on approved medicines and indications as defined by the sponsor specific information on ClinicalStudyDataRequest.com This access is provided in a timely fashion after the primary publication is accepted. Researchers need to have an approved research proposal submitted through ClinicalStudyDataRequest.com. Access to the data will be provided in a secure data sharing environment after signing a data sharing agreement.

URL: <http://>

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Eli Lilly and Company:
insulin pump

Additional relevant MeSH terms:
Diabetes Mellitus

Immune System Diseases