I protocolli di ricerca a livello internazionale

La Dichiarazione di Helsinki, che riporta i principi della *World Medical Association* per la ricerca sugli esseri umani e che è il riferimento fondamentale per il protocollo di tutte le sperimentazioni cliniche, riporta che

“Ogni studio di ricerca che coinvolge esseri umani deve essere registrato in un database pubblicamente accessibile prima dell’arruolamento del primo partecipante”.

I Registri (di sperimentazioni cliniche e non solo)

I registri sono banche dati pubbliche (consultabili su Internet) che raccolgono e offrono informazioni sulle **sperimentazioni cliniche** in corso o concluse

I ricercatori pubblicano sul registro un protocollo di ricerca → viene di conseguenza assegnato al protocollo un numero identificativo unico

Il registro mette a disposizione i protocolli pubblicati a tutti i ricercatori attraverso motori di ricerca

Strumenti di sorveglianza epidemiologica nati con l'obiettivo di:

- Facilitare la diffusione delle informazioni
- Aumentare la trasparenza → ad es evitando che studi con risultati negativi non siano divulgati

  → riducendo il publication bias

  → consentendo di prendere decisioni sull'assistenza sanitaria che siano supportate da tutte le evidenze disponibili

  → limitando la possibilità di cambiare in corsa

- Evitare la duplicazione degli studi clinici e prevenire il finanziamento di ricerche simili a quelle già in atto
- Identificare gap nella ricerca clinica grazie alla descrizione della ricerca in corso
- Promuovere la collaborazione tra ricercatori
- Favorire il reclutamento dei pazienti nelle sperimentazioni in corso rendendole pubbliche
- Permettere l'identificazione precoce di potenziali problemi metodologici

Nel 2005 l'International Committee of Medical Journal Editors (ICMJE) ha deciso che nessun trial sarebbe stato accettato per la pubblicazione se non fosse stato registrato in un registro pubblico

Le più importanti riviste scientifiche non accettano sperimentazioni cliniche per la pubblicazione se queste non sono state registrate prima dell'avvio dell'arruolamento

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

14 riviste sono membri ufficiali …

Member Publications & Organizations

… ma 2500+ seguono le sue raccomandazioni

Registri Internazionali (riconosciuti da ICMJE)

- Australia and New Zealand's (ANZCTR) (http://www.anzctr.org.au)
- Brazilian Clinical Trials Registry (ReBec) (http://www.ensaiosclinicos.gov.br)
- Chinese Clinical Trial Registry (ChiCTR) (http://www.chictr.org)
- Clinical Research Information Service (CRiS), Republic of Korea (http://cris.cdc.go.kr)
- Clinical Trials Registry - India (CTRI) (http://ctri.nic.in)
- Cuban Public Registry of Clinical Trials(RPCEC) (http://registroclinico.sld.cu)
- EU Clinical Trials Register (EU-CTR) (https://www.clinicaltrialsregister.eu/)
- German Clinical Trials Register (DRKS) (http://www.drks.de)
- Iranian Registry of Clinical Trials (IRCT) (http://www.irct.ir/)
- Japan's UMIN-CTR (http://umin.ac.jp)
- Thai Clinical Trials Registry (www.clinicaltrials.in.th)
- The Netherlands' Trialregister.nl
- The United States' ClinicalTrials.gov
- The International ISRCTN.org
- Pan African Clinical Trial Registry (PACTR) (http://www.pactr.org/)
- Sri Lanka Clinical Trials Registry (SLCTR) (http://www.slctr.lk/)

In Italia

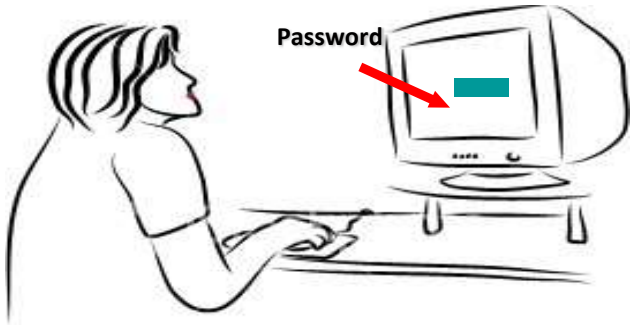
Osservatorio nazionale sulla sperimentazione clinica dei medicinali (**OsSC**) → AIFA → registrazione obbligatoria di sperimentazioni cliniche in cui vengono impiegati medicinali

Osservatorio Nazionale Sperimentazione Clinica

L'**Osservatorio Nazionale sulla Sperimentazione Clinica dei medicinali** (OsSC) raccoglie le informazioni sulle sperimentazioni cliniche (fase I-IV) svolte in Italia dal 2000.

L'OsSC rappresenta un modello di banca dati sulla sperimentazione clinica dei medicinali, per quanto riguarda la gestione della documentazione fra Regioni, autorità competenti, Comitati Etici, promotori, centri clinici e banca dati Europea EudraCT.

Strumento di sorveglianza epidemiologica su tutte sperimentazioni cliniche condotte in Italia



OsSC e Ricerca Clinica

Osservatorio Nazionale Sperimentazione Clinica

Dal 2010

Observational Studies Register

Nel 2011…

RICERCA CLINICA

Agenzia Italiana del Farmaco AIFA

Il Portale della Ricerca Clinica sui Farmaci in Italia

Il Portale della Ricerca Clinica sui Farmaci del'AIFA è **una fonte di informazione pubblica** sulle sperimentazioni cliniche dei medicinali condotte in Italia, sulle norme ed i principi etici che regolano la ricerca, sulle iniziative in materia di sperimentazione promosse dall'AIFA.

ha l'obiettivo di aumentare la trasparenza e di promuovere la conoscenza sulla ricerca clinica farmacologica a beneficio dei pazienti, della comunità scientifica e del pubblico in generale.

https://www.agenziafarmaco.gov.it/ricclin/it/ricercaStudiClinici#

EU Clinical Trials Register

https://www.clinicaltrialsregister.eu/ctr-search/search

Permette di ricercare informazioni nel database EudraCT → utilizzato dalle agenzie regolatorie nazionali europee (es AIFA) per inserire dati relativi a protocolli di trials

OSsC → **Eudract** → **EU Clinical Trials Register**

EU Clinical Trials Register

Fase 1	**1.296**
Fase 2	**11.484**
Fase 3	**9.555**
Fase 4	**6.763**
Totale	**27.391**

Italia: 6.203 sperimentazioni

Ricerca aggiornata al 23.02.2016

ClinicalTrials.gov → U.S. National Institute of Health

Interventistici: **168.369**

Fase 0	**1.681**
Fase 1	**31.583**
Fase 2	**45.886**
Fase 3	**29.481**
Fase 4	**21.269**

Osservazionali: **39.644**

Totale: **208.959**

Ricerca aggiornata al 23.02.2016

International Clinical Trials Registry Platform (ICTRP)

→ Portale gestito da WHO

Database centrale che contiene registrazioni di trial provenienti da più registri

Riceve aggiornamenti settimanali da:

Australian New Zealand Clinical Trials Registry

Chinese Clinical Trial Registry

ClinicalTrials.gov

EU Clinical Trials Register (EU-CTR)

ISRCTN

The Netherlands National Trial Register

Riceve aggiornamenti mensili da:

Brazilian Clinical Trials Registry (ReBec)

Clinical Trials Registry – India

Clinical Research Information Service - Republic of Korea

Cuban Public Registry of Clinical Trials

German Clinical Trials Register

Iranian Registry of Clinical Trials

Japan Primary Registries Network

Pan African Clinical Trial Registry

Sri Lanka Clinical Trials Registry

Thai Clinical Trials Register (TCTR)

http://apps.who.int/trialsearch/

File Modifica Visualizza Cronologia Segnalibri Strumenti Aiuto

Clinical Trials register | EudraCT Public website - Home pa... | Connessione... | ICTRP Search Portal

apps.who.int/trialsearch/

Cerca

World Health Organization

International Clinical Trials Registry Platform
Search Portal

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

Example: liver cancer OR breast cancer NOT genetic

Search | Search tips

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)
- Call for public Consultation (closed): WHO Statement on Public Disclosure of Clinical Trial Results More information

Data Providers

Data sets from data providers are updated every Wednesday evening according to the following schedule:
Every week:

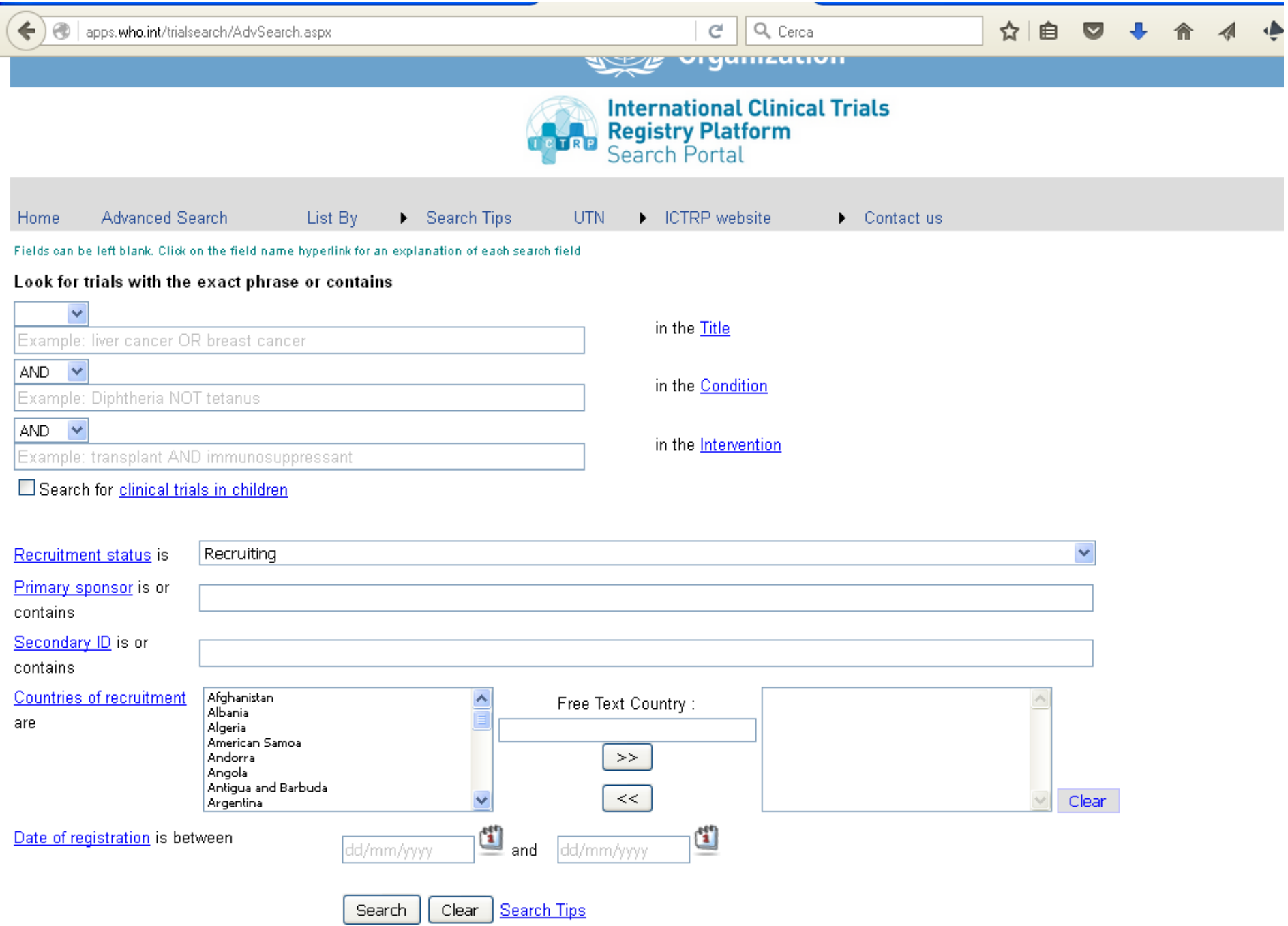
- Australian New Zealand Clinical Trials Registry, last data file imported on **15 February 2016**
- Chinese Clinical Trial Registry, last data file imported on **15 February 2016**
- ClinicalTrials.gov, last data file imported on **15 February 2016**
- EU Clinical Trials Register (EU-CTR), last data file imported on **15 February 2016**
- ISRCTN, last data file imported on **15 February 2016**
- The Netherlands National Trial Register, last data file imported on **15 February 2016**

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on **2 February 2016**
- Clinical Trials Registry - India, last data file imported on **2 February 2016**
- Clinical Research Information Service - Republic of Korea, last data file imported on **2 February 2016**
- Japan Primary Registries Network, last data file imported on **2 February 2016**

361.647 records for 306.766 trials found!

Ricerca aggiornata al 23.02.2016


apps.who.int/trialsearch/AdvSearch.aspx
Cerca
International Clinical Trials Registry Platform
Search Portal
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
Recruiting
Primary sponsor is or contains
Secondary ID is or contains
Countries of recruitment are
Afghanistan
Albania
Algeria
American Samoa
Andorra
Angola
Antigua and Barbuda
Argentina
Free Text Country :
>>
<<
Clear
Date of registration is between
dd/mm/yyyy
and
dd/mm/yyyy
Search
Clear
Search Tips

World Health Organization

International Clinical Trials Registry Platform
Search Portal

Back to Search

Export results to XML

4 records for 3 trials found for: ondansetron and domperidone (What is this?)

Show 10 records per page

Recruitment status	Main ID	Public Title	Date of Registration
Not Recruiting	TCTR20120000011	Oral ondansetron for vomiting treatment in children with acute gastroenteritis	21/05/2012
Not recruiting	NCT01257672	Symptomatic Treatment of Acute Gastroenteritis	09/12/2010
Recruiting	JPRN-UMIN000001813	Ramdomized phasell trial of concurrent antiemetics with oral rehydration therapy for children with vomiting in the result of acute gastroentiritis	30/03/2009

World Health Organization

International Clinical Trials Registry Platform
Search Portal

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

Back to Search | Export results to XML

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Recruitment status	Main ID	Public title	Date of registration
Authorised	EUCTR2010-019787-36-IT	ORAL ONDANSETRON VS DOMPERIDONE FOR SYMPTOMATIC TREATMENT OF VOMITING DURING ACUTE GASTROENTERITIS IN CHILDREN: MULTICENTRE RANDOMIZED CONTROLLED TRIAL - SYMPTOMATIC TREATMENT OF ACUTE GASTROENTERITIS	24/12/2010

Main

Note: This record shows only the 20 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ClinicalTrials.gov
Last refreshed on:	19 February 2015
Main ID:	NCT01257672
Date of registration:	09/12/2010
Primary sponsor:	IRCCS Burlo Garofolo
Public title:	Symptomatic Treatment of Acute Gastroenteritis
Scientific title:	Oral Ondansetron vs Domperidone for Symptomatic Treatment of Vomiting During Acute Gastroenteritis in Children: Multicentre Randomized Controlled Trial
Date of first enrolment:	July 2011
Target sample size:	356
Recruitment status:	Completed
URL:	http://clinicaltrials.gov/show/NCT01257672
Study type:	Interventional
Study design:	Allocation: Randomized, Endpoint Classification: Safety/Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Primary Purpose: Treatment
Phase:	Phase 3

Countries of recruitment

Italy

Contacts

Name:	Federico Marchetti, MD	**Name:**	Maurizio Bonati, MD
Address:		**Address:**	
Telephone:		**Telephone:**	
Email:		**Email:**	
Affiliation:	IRCCS Burlo Garofolo	**Affiliation:**	Mario Negri Institute for Pharmacological Research

Key inclusion & exclusion criteria

Inclusion Criteria:

1. age from 1 to 6 years;

Main

Note: This record shows only the 20 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	EUCTR
Last refreshed on:	19 March 2012
Main ID:	EUCTR2010-019787-36-IT
Date of registration:	24/12/2010
Primary sponsor:	ISTITUTO PER L'INFANZIA BURLO GAROFOLO
Public title:	ORAL ONDANSETRON VS DOMPERIDONE FOR SYMPTOMATIC TREATMENT OF VOMITING DURING ACUTE GASTROENTERITIS IN CHILDREN: MULTICENTRE RANDOMIZED CONTROLLED TRIAL - SYMPTOMATIC TREATMENT OF ACUTE GASTROENTERITIS
Scientific title:	ORAL ONDANSETRON VS DOMPERIDONE FOR SYMPTOMATIC TREATMENT OF VOMITING DURING ACUTE GASTROENTERITIS IN CHILDREN: MULTICENTRE RANDOMIZED CONTROLLED TRIAL - SYMPTOMATIC TREATMENT OF ACUTE GASTROENTERITIS
Date of first enrolment:	04/07/2011
Target sample size:	
Recruitment status:	Authorised-recruitment may be ongoing or finished
URL:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2010-019787-36
Study type:	Interventional clinical trial of medicinal product
Study design:	Controlled: yes Randomised: yes Open: no Single blind: no Double blind: yes Parallel group: yes Cross over: no Other: no If controlled, specify comparator, Other Medicinial Product: yes Placebo: yes Other: no
Phase:	

Countries of recruitment

Italy

Contacts

Principale limite:

- Quasi solo trial clinici → pubblicazione del protocollo di studi osservazionali non obbligatoria → rappresentano circa il 90% degli studi pubblicati

- Non esiste al momento un registro internazionale dedicato agli studi osservazionali

  → alcuni registri lasciano questa possibilità (Clinicaltrials.gov ~ 20%)

- Esistono registri che raccolgono protocolli di revisioni sistematiche

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for Health Research

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My details
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Latest news

PROSPERO registrations reach milestone

Thanks to the enthusiastic response from the international research community there are now over 10,000 records available in PROSPERO.

By prospectively submitting systematic review protocol details to PROSPERO registrants are helping reduce unplanned duplication and increasing transparency, helping safeguard against selective reporting; making it possible for editors, peer reviewers and others to compare planned methods with the final report.

Read more...

Latest new and updated records

Systematic review and meta-analyses of sensitivity and specificity of real-time polymerase chain reaction in the diagnosis of maternal anogenital colonization by group B streptococcus during labor

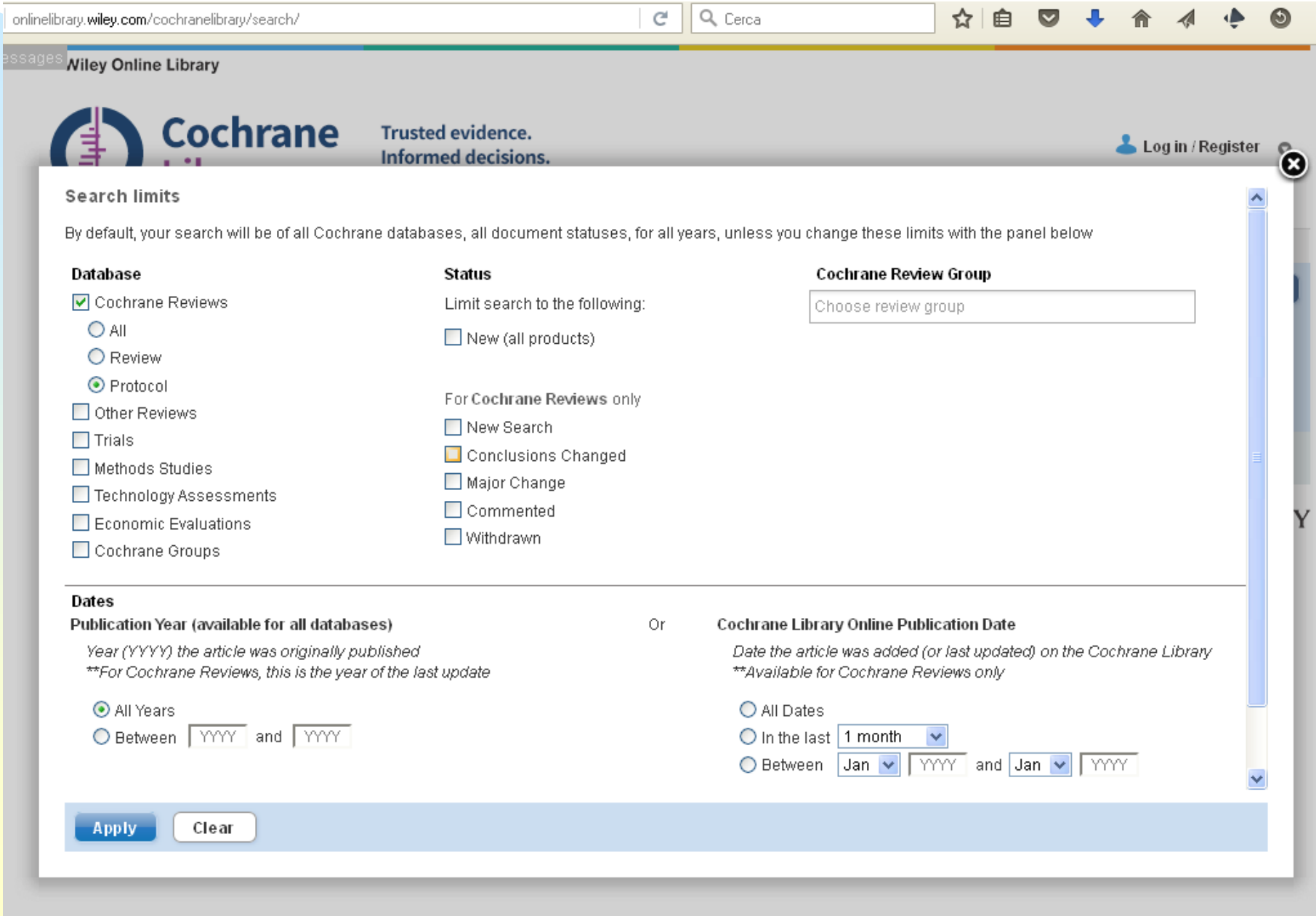
Intranasal dexmedetomidine as sedative premedication for children: protocol for a systematic review

Medication adherence and apparent-treatment resistant hypertension: systematic review and meta-analysis

Rate of return to sport of overhead athletes after ulnar collateral ligament reconstruction

Association of apical periodontitis with tumor necrosis factor alpha gene polymorphisms: a systematic review and meta-analysis

La Cochrane library pubblica i protocolli delle revisioni



International Clinical Trials Registry Platform (ICTRP)

Primary Registries

Share Print

Primary Registries in the WHO Registry Network

Primary Registries in the WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the ICMJE.

The registries that currently meet these criteria are:

Australian New Zealand Clinical Trials Registry (ANZCTR)	Profile	Website
Brazilian Clinical Trials Registry (ReBec)	Profile	Website
Chinese Clinical Trial Registry (ChiCTR)	Profile	Website
Clinical Research Information Service (CRiS), Republic of Korea	Profile	Website
Clinical Trials Registry - India (CTRI)	Profile	Website
Cuban Public Registry of Clinical Trials(RPCEC)	Profile	Website
EU Clinical Trials Register (EU-CTR)	Profile	Website
German Clinical Trials Register (DRKS)	Profile	Website
Iranian Registry of Clinical Trials (IRCT)	Profile	Website
ISRCTN.org	Profile	Website
Japan Primary Registries Network (JPRN)	Profile	Website(in Japanese) Network members: UMIN CTR Website JapicCTI Website JMACCT CTR Website
Thai Clinical Trials Registry (TCTR)	Profile	Website
The Netherlands National Trial Register (NTR)	Profile	Website
Pan African Clinical Trial Registry (PACTR)	Profile	Website
Sri Lanka Clinical Trials Registry (SLCTR)	Profile	Website

Clinical Trial Registration

The ICMJE's clinical trial registration policy is detailed in a series of editorials (see Updates and Editorials and FAQs).

Briefly, the ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Editors requesting inclusion of their journal on the ICMJE website list of publications that follow ICMJE guidance should recognize that the listing implies enforcement by the journal of ICMJE's trial registration policy.

The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention *and* a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE does not define the timing of first patient enrollment, but best practice dictates registration by the time of first patient consent.

The ICMJE accepts registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. The ICMJE endorses these registries because they meet several criteria. They are accessible to the public at no charge, open to all prospective registrants, managed by a not-for-profit organization, have a mechanism to ensure the validity of the registration data, and are electronically searchable. An acceptable registry must include the minimum 20-item trial registration dataset (http://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf or www.who.int/ictrp/network/trds/en/index.html) at the time of registration and before enrollment of the first participant. The ICMJE considers inadequate trial registrations missing any of the 20 data fields or those that have fields that contain uninformative information. Although not a required item, the ICMJE encourages authors to include a statement that indicates that the results have not yet been published in a peer-reviewed journal, and to update the registration with the full journal citation when the results are published.

The purpose of clinical trial registration is to prevent selective publication and selective reporting of research outcomes,