AdisInsight: Trials

AdisInsight: Trials (formerly Adis Clinical Trials Insight) is a leading source of in-depth and up-to-date clinical trial data, with coverage of both international and observational trials. Quickly identify the key clinical trials being performed to advance drugs in commercial development through international regulatory pathways.

Profiles include:

- Phase of trial and current status
- Trial purpose, focus and design
- Primary and other endpoints
- Diseases and subjects treated
- Inclusion and exclusion criteria
- Trial identifiers
- Organizations involved
- Initiation, completion and end dates
- Interventions
- Study center and investigator details
- Trial history
- Outcomes and results
- Related authors

Highly structured evaluations of key papers from international biomedical journals and conferences cover clinical data and trials in the following areas:

Affective Disorders
Alzheimer's, Cognition Disorders
Antibacterials
Antithrombotics
Antivirals
Anxiety Disorders
Arrhythmias
Cancer Chemotherapy
Cardiovascular Disorders
Congenital Disorders
Connective Tissue Disorders
Diabetes
Digestive System Disorders
Ear, Nose and Throat Disorders
Endocrine Disorders
Epilepsy and Seizure Disorders
Eye Disorders
Genitourinary Disorders
Haematological Disorders
Heart Failure
Hyperlipidaemia
Hypertension
Immunological Disorders
Inflammation
Irritable Bowel Syndrome
Ischaemic Heart Disease
Liver Disorders
Men's Health
Metabolic Disorders
Mouth Disorders
Musculoskeletal Disorders
Mycoses
Nausea & Migraine
Neurological Disorders
Nutritional Disorders
Obesity
Obstructive Airways Disease
Pain Control
Parasitic Infections
Parkinson's Disease
Peptic Ulcer Disease
Psychotic Disorders
Respiratory Tract Disorders
Rheumatic Disease
Skin Disorders
Thrombosis and Embolism
Transplant Rejection
Vaccines
Vascular Disorders
Viral Infections
Women's Health

Date Coverage
1990–present

Update Frequency
Weekly

Geographic Coverage
International

Document Types
Full text of Adis evaluations

Publisher

ADISInsight: Trials is produced by Springer Healthcare.

Date revised: 1 December 2020

AdisInsight: Trials

Full text « Back to results

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TI A Phase 2b Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants

PUB, PD, YR **AdisInsight: Trials** (Sep 1, 2016).

TX **Full Text** Translate

Study Design:
double-blind, multicentre, parallel, prospective, randomised

Study Endpoints:

Incidence of hospitalization due to RT-PCR confirmed RSV
safety issue: No
description: The incidence of RSV hospitalization 150 days post dose will be summarized by treatment group.
time frame: 150 days post dose

Safety and tolerability as assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatement emergent serious adverse events (TESAE)
safety issue: Yes
description: Safety of MEDI88987 will primarily be assessed and measured by the occurrence of all treatment-emergent AEs and SAEs.
Other safety assessments will include the occurence of AESIs and NOCDs.
time frame: 360 days post dose

Single-dose serum concentrations of MEDI8897
safety issue: No
description: MEDI8897 serum concentration data will be tabulated by treatment group along with descriptive statistics. Terminal-phase half-life (t1/2) will be estimated using non-compartmental analysis, if data permit.
time frame: 360 days post dose

Incidence of anti-drug antibody (ADA) to MEDI8897 in serum
safety issue: No
description: The incidence of ADA to MEDI8897 will be assessed and summarized by number and percentage of subjects that are ADA positive by treatment group.
time frame: 360 days post dose

Incidence of medically attended LRTI due to RT-PCR confirmed RSV
safety issue: No
description: The incidence of RSV LRTI (inpatient and outpatient) 150 days post dose will be based on RSV test results (performed centrally via RT-PCR) and objective clinical LRTI criteria and will be summarized by treatment group.
time frame: 150 days post dose

Study Details:

Status: initiated
Planned Start: September 2016
Planned Finish: April 2018
Design: double-blind, multicentre, parallel, prospective, randomised
Phase: II
Endpoints:
Incidence of hospitalization due to RT-PCR confirmed RSV
safety issue: No
description: The incidence of RSV hospitalization 150 days post dose will be summarized by treatment group.
time frame: 150 days post dose
Safety and tolerability as assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatement emergent serious adverse events (TESAE)
safety issue: Yes
description: Safety of MEDI88987 will primarily be assessed and measured by the occurrence of all treatment-emergent AEs and SAEs.
Other safety assessments will include the occurence of AESIs and NOCDs.
time frame: 360 days post dose
Single-dose serum concentrations of MEDI8897
safety issue: No
description: MEDI8897 serum concentration data will be tabulated by treatment group along with descriptive statistics. Terminal-phase half-life (t1/2) will be estimated using non-compartmental analysis, if data permit.
time frame: 360 days post dose
Incidence of anti-drug antibody (ADA) to MEDI8897 in serum
safety issue: No
description: The incidence of ADA to MEDI8897 will be assessed and summarized by number and percentage of subjects that are ADA positive by treatment group.
time frame: 360 days post dose,
Incidence of medically attended LRTI due to RT-PCR confirmed RSV
safety issue: No
description: The incidence of RSV LRTI (inpatient and outpatient) 150 days post dose will be based on RSV test results (performed centrally via RT-PCR) and objective clinical LRTI criteria and will be summarized by treatment group.
time frame: 150 days post dose
Study Center: MedImmune LLC
Companies: MedImmune

Subject Details:

Planned No: 1500
Location: Argentina, Australia, Belgium, Brazil, Bulgaria, Canada, Chile, Czech Republic, Finland, France, Germany, Hungary, Italy, Multinational, New Zealand, Poland, Russia, South Africa, Spain, Sweden, United Kingdom, USA
Disease: Respiratory-syncytial-virus-infections
Patient Inclusion: Key 1. Healthy infants born between 29 weeks 0 days and 34 weeks 6 days GA 2. Infants who are entering their first full RSV season at the time of screening Key
Patient Exclusion: 1. Meets AAP or other local criteria to receive commercial palivizumab 2. Any fever (≥ 100.4°F [≥ 38.0°C], regardless of route) or lower respiratory illness within 7 days prior to randomization 3. Acute illness (defined as the presence of moderate or severe signs and symptoms) at the time of randomization 4. Active RSV infection (a child with signs/symptoms of respiratory infection must have negative RSV testing) or known prior history of RSV infection 5. Receipt of palivizumab or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccinationPlanned Patient Number: 1500
Patient Age Keywords: infant, neonate

REF **References**

1.) ClinicalTrials.gov: US National Institutes of Health

WC Word count: **675**

Indexing (details) Cite

SU	Subject	Antivirals; MEDI-8897; Respiratory-syncytial-virus-infections, prevention
	Related record	ADRD accession number: .
TI	Title	A Phase 2b Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants
LA	Language	English
DTYPE	Document type	Ongoing Trial
PUB	Publication title	AdisInsight: Trials
PSTYPE	Publication type	Scholarly journals
STI	Clinical trial ID	700275673 (Clinical Trials Insight), D5290C00003(), NCT02878330 (ClinicalTrials.gov: US National Institutes of Health)
PD,YR	Publication date	Sep 1, 2016
AN	Accession number	700275673
	Document URL	http://dialog.proquest.com/professional/docview/1815600143?accountid=174335
FAV	First available	2016-09-01
UD	Updates	2016-09-01
	Database	AdisInsight: Trials (1990 - current)

Search Fields

Field Name	Field Code	Example	Description and Notes
Accession number	AN	an(700275673)	A unique document identification number assigned by the information provider.
All fields	ALL	all(palivizumab)	Searches all fields *except* the full text. Use proximity and/or Boolean operators to narrow search results.
All fields + text	--	palivizumab	Searches all fields including the full text.
Author[1]	AU	au(kavanaugh)	Authors are included in the citation information of 'Best Evidence' documents. Also present in 'Citation only' documents, available until 2010 only.
First author	FAU	fau(mease)	The first author is searchable in its own field, FAU.

[1] A Lookup/Browse feature is available for this field in the Advanced Search dropdown or in Browse Fields.

Field Name	Field Code	Example	Description and Notes
Author affiliation	AF	af("columbia university") tx("montefiore headache center")	Author affiliations are included in the citation information of some 'Best Evidence' documents. Also present in 'Citation only' documents, available until 2010 only. Some author affiliations are displayed at the end of text and are searchable with TX.
Clinical trial ID	STI	sti(11416) sti(ccrn622) sti(cain457f2306) sti(eudra*) sti(nct*)	The identifiers of published clinical trials, usually available in 'Best evidence' documents, appear here. Search the full identifier or use the asterisk to truncate your entry.
Conference information	CF	cf(american headache society 2015)	Some 'Best evidence' documents refer to the conference in which the trial was discussed. The conference title is searchable with CF or CFTI.
Conference title	CFTI	cfti(american headache society 2015)	Some 'Best evidence' documents refer to the conference in which the trial was discussed. The conference title is searchable with CF or CFTI.
Document text			See Text
Document title			See Title
Document type	DTYPE	dtype(best evidence) dtype(ongoing trial)	The two commonest document types are 'Ongoing trial' and 'Best evidence'. A number of 'Citation only' documents, describing trials cited in journal articles, are included up to 2010. 'Ongoing trial' documents describe trials which are in process; 'Best evidence' documents describe completed trials. Both types of document include a full Adis evaluation of the trial, and in the case of 'Best evidence' the citation of the publication in which the trial appeared as well. 'Citation only' documents do not include any evaluation of the trial.
First available	FAV	fav(2016-09-01)	Indicates the first time a document was on Dialog. It will not change regardless of how many times the record is subsequently reloaded, as long as the accession number does not change.
From database[2]	FDB	ti(bleomycin) AND fdb(1008200) ti(bleomycin) AND fdb(clinicaltrialsinsight)	Useful in multi-file searches to isolate records from a single file. FDB cannot be searched on its own; specify at least one search term then AND it with FDB.

[2] Click the "Field codes" hyperlink at the top right of the Advanced Search page. Click "Search syntax and field codes", then click on "FDB command" to get a list of database names and codes that can be searched with FDB.

Field Name	Field Code	Example	Description and Notes
ISSN	ISSN	issn(0028-4793)	ISSNs are included in the citation information of 'Best Evidence' documents, when they refer to journal articles. Also present in 'Citation only' documents, available until 2010 only.
Issue	ISS	iss(14)	Issue numbers are included in the citation information of 'Best Evidence' documents, when they refer to journal articles. Also present in 'Citation only' documents, available until 2010 only.
Language	LA	la(english)	Almost all source documents are in English
Pagination	PG	pg(1329-39)	Pagination is included in the citation information of 'Best Evidence' documents, when they refer to journal articles. Also present in 'Citation only' documents, available until 2010 only.
Publication date	PD	pd(20160901) pd(>20150630)	A single publication date or a range of dates may be searched.
Publication title[1]	PUB	pub(adisinsight trials) pub(adis*) pub(new england journal of medicine)	The publication title of 'Best Evidence' documents is the name of the journal in which the trial information was published. In 'Ongoing Trial' documents, the publication title is 'AdisInsight: Trials' or its former name 'Adis Clinical Trials Insight'.
Publication type	PSTYPE	pstype(scholarly journals)	The Publication type is the same for all documents in this database.
Publication year	YR	yr(2016) yr(>2010)	A single year or a range of years may be searched.
References	REF	ref("clinicaltrials.gov")	References to the repositories holding the clinical trial information.
Route of administration	RO	ro(iv) ro(oral)	The route of administration is available in some documents and is displayed with the drug information in the Substance field.
Source information	SRC	src(lancet)	The source information, including publication title, volume, issue, ISSN, publication date, and pagination, is all searchable with SRC. It will retrieve 'Best Evidence' and pre-2010 'Citation Only' documents.
Study identifier			See Clinical trial ID
Subject[1]	SU	su(antivirals) su("rheumatic disease") su("skin disorders") su(secukinumab)	The main subjects discussed in the document are presented here. Search with proximity operators or double quotes for a known precise phrase.
Substance[1]	SUBST	subst(secukinumab)	'Best evidence' documents include the generic names of drugs discussed in the article, and they are searchable with the SUBST code. The route of administration is also displayed in Substance, but it is only searchable with the RO field code.

Field Name	Field Code	Example	Description and Notes
Text	TX	tx(rsv near vaccin*) tx("monoclonal antibody")	The Adis evaluation of the trial is provided here, with structured sections on study design, endpoints, status, subjects and other details. Use proximity and/or Boolean operators to narrow or broaden search results. Use double quotes for a specific phrase.
Therapeutic classification *Available until June 2014 only*	TC	tc(j04*) tc(j04am02)	EphMRA ATC and WHO ATC classification codes were included in documents up to June 2014. If you include it in a search you will limit retrieval to material before that date.
Title	TI	ti(respiratory syncytial virus) ti(secukinumab AND psoriatic arthritis)	Use adjacency and/or Boolean operators to narrow search results.
Title only	TIO	tio(secukinumab)	Searches only the Title, not the Alternate title.
Alternate title	OTI	oti(step stop trial)	An Alternate title is available in some documents, containing other names by which the study may be known. Field code TI also searches the Alternate title.
Updates	UD	ud(2016-09-01)	The date(s) the record was loaded or updated on Dialog. The latest date is at the bottom.
Volume	VO	vo(373)	The Volume is included in the citation information of 'Best Evidence' documents, when they refer to journal articles. Also present in 'Citation only' documents, available until 2010 only.

Search Tools

Field codes are used to search document fields, as shown in the sample document. Field codes may be used in searches entered on the **Basic Search**, **Advanced Search**, and **Command Line** search pages. **Limit options**, **Look up** lists, and "Narrow results by" filters tools are available for searching. Some data can be searched using more than one tool.

Limit Options

Limit options are quick and easy ways of searching certain common concepts. Short lists of choices are available for:

Document type and **Language**

Date limiters are available in which you can select single dates or ranges for date of **publication** and **updated**.

Look up Lists

You can browse the contents of certain fields by using Look Up lists. These are particularly useful to validate spellings or the presence of specific data. Terms found in the course of browsing may be selected and automatically added to the Advanced Search form. Look Up lists are available in the fields drop-down and in the search options for:

Subject, Substance, and Author

and in the fields drop-down only for:

Publication title

"Narrow Results By" Filters

When results of a search are presented, the results display is accompanied by a list of "Narrow results by" options shown on the right-hand panel. Click on any of these options and you will see a ranked list showing the most frequently occurring terms in your results. Click on the term to apply it to ("narrow") your search results. Narrow results by filters in Adis Clinical Trials include:

Subject, Substance, Author, Publication title, Document type, Publication date

Look up Citation

If you need to trace a particular bibliographic reference, use the Look Up Citation feature. Find a link to this toward the top left of the Advanced Search page, or in the drop list under Advanced on any search form; click this and you will go to a page where you can enter any known details of the citation, including: Document title, Author, Publication title, ISSN, ISBN, Volume, Issue, Page, Publication date, DOI.

Document Formats

Pre-defined document formats are available for viewing and download. Search results can be downloaded with the Download all results, Email, Print and Export/Save options, and when creating an alert. To design your own download format, choose the "Custom" format option and check the fields to be displayed.

Document Format	Fields	Online	Export/Download
Brief view	Title and Publication date.	✓	
Detailed view	**Brief view** plus a 3-line KWIC window.	✓	
KWIC (Keyword in Context)	**Detailed view** plus all occurrences of your search terms, highlighted in fields where the terms appear.	✓	✓
Preview	**Detailed view** plus Publication title and Subject.	✓	
Brief citation	Title, Publication date and partial indexing.	✓	✓
Full text	The complete document.	✓	✓
Custom	Choose the fields you want.		✓[3]

[3] Custom export/download format is available in the following mediums only: HTML, PDF, RefWorks, RTF, Text only, XLS.

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