AN OPEN LABEL EXTENSION STUDY TO ASSESS THE LONG TERM SAFETY OF ETANERCEPT IN CHILDREN AND ADOLESCENTS WITH EXTENDED OLIGOARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, ENTHESITIS RELATED ARTHRITIS, OR PSORIATIC ARTHRITIS WHO WERE PREVIOUSLY ENROLLED IN PROTOCOL 0881A1 3338 WW(B1801014)

Published: 03-11-2011
Last updated: 30-04-2024

Primary* To monitor the occurrence of malignancy in pediatric subjects with extended oligoarticular JIA, ERA, or PsA.Secondary* To assess the long-term safety profile of etanercept.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON37419

Source
ToetsingOnline

Brief title
B1801023 - Clipper 2 (Juvenile Arthritis)

Condition

- Autoimmune disorders
- Joint disorders
- Epidermal and dermal conditions

Synonym
Juvenile idiopathic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Enthestitis related arthritis, Etanercept Open Label Extension, Oligoarticular JIA, Psoriatic arthritis

Outcome measures

Primary outcome

* Occurrence of malignancy.

Secondary outcome

* Occurrence of serious adverse events;

* Occurrence of medically important infections (ie, an infection requiring

hospitalization and /or parenteral [intravenous (IV), intra-muscular (IM)]

anti-infective agents).

Additional Key Secondary Endpoints for Subjects in the Active Treatment Period

* Occurrence of all adverse events, including infections, infections considered

preventable by vaccination, and injection site reactions;

* Occurrence of withdrawals from investigational product due to adverse events;

* Laboratory evaluations;

* Growth parameters;

* Tanner Stage Assessment for selected subjects.

Other Secondary Endpoints for Subjects in the Active Treatment Period

* Physician*s Global Assessment (PGA) of Disease Activity on a 21-circle visual analogue scale (VAS);

* Patient/Parent Global Assessment on a 21-circle VAS;

* C-reactive protein (CRP).

Health Outcomes Assessment for Subjects in the Active Treatment Period

* Childhood Health Assessment Questionnaire (CHAQ): for subjects aged <18 years at the time of assessment;

* Health Assessment Questionnaire (HAQ): for subjects aged >18 years at the time of assessment.

Study description

Background summary

Juvenile idiopathic arthritis (JIA) is the most common autoimmune-autoinflammatory disease in childhood and affects approximately 1 in 1,000 children. Despite advances in diagnosis and treatment options, JIA remains a chronic condition for most affected children. Etanercept is approved by both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to treat pediatric patients with polyarticular JIA aged 4 years and above, who have had an inadequate response to, or who have proved intolerant of, methotrexate.

Protocol 0881A1-3338 was designed to assess the clinical benefit and the

long-term safety of etanercept for 2 years in pediatric subjects with extended oligoarticular JIA, ERA or PsA.

Protocol B1801023 is an 8-year extension study designed to further characterize the long-term safety profile, malignancy and other serious adverse events, for those pediatric subjects who received at least one dose of etanercept and completed 96 weeks of investigational product and/or follow-up in study 0881A1-3338.

Study objective

Primary
* To monitor the occurrence of malignancy in pediatric subjects with extended oligoarticular JIA, ERA, or PsA.
Secondary
* To assess the long-term safety profile of etanercept.

Study design

This is an open-label, single treatment, multi-center, 8-year extension study.

Intervention

Active treatment period:
* Subjects who completed approximately 96 weeks of active treatment with investigational product (etanercept) in study 0881A1-3338 and are eligible to continue investigational product in study B1801023 will enter directly into the active treatment period. These subjects may continue to receive investigational product for up to 8 additional years (96 months).

Observational period:
* Subjects who discontinue investigational product prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or who are not eligible to continue investigational product in study B1801023 will not be permitted to re-start investigational product in study B1801023 and will enter directly into the observational period of study B1801023. These subjects will be observed for up to 8 years (96 months).
* Subjects who participate in the active treatment period of study B1801023 and subsequently discontinue use of investigational product at any time before completion of the study will be transferred from the active treatment period to the observational period, and will be followed in the observational period for up to a total of 8 years (96 months) from the time of initial entry into study B1801023. Once a subject enters into the observational period after discontinuing from the active treatment period, he or she cannot resume investigational product for the remaining time in the study. Subjects participating in the observational period of study B1801023 will receive

standard of care including any anti-TNF agents (eg, commercial etanercept) and/or other biologic agents for treatment of their disease at the discretion of the investigator.

Study burden and risks

There is over 10 years experience with the product etanercept in adults. Meanwhile, there is also experience in children, according to both label and off-label.
In the current study, etanercept is added to existing treatment (treatment arm) or patients are observed only. The additional load consists of keeping diaries and more visits to the outpatient clinic, where questionnaires are to be completed.

Contacts

Public
Pfizer

235 East 42nd Street
NY 10017
US
Scientific
Pfizer

235 East 42nd Street
NY 10017
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

* Receipt of at least 1 dose of investigational product (etanercept) and participation for approximately 96 weeks in study 0881A1-3338 (B1801014)
* Personally signed and dated informed consent document (and assent document, as applicable) indicating the subject (or legally authorized representative/guardian) has been informed of all pertinent aspects of the study.;Please see the protocol, section 4.1, for a complete list of inclusion criteria

Exclusion criteria

* Withdrawal from investigational product in study 0881A1-3338 for any reason (safety or non-safety).
* History of maliginancy other than squamous cell, basal cell carcinoma or cervical carcinoma in situ.;Please see the protocol, section 4.2, for a complete list of exclusion criteria

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2012
Enrollment:	3
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Enbrel
Generic name:	Etanercept
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-05-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-10-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-05-2014
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-01-2019
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-023802-10-NL
ClinicalTrials.gov	NCT01421069
CCMO	NL38158.041.11

Study results

Date completed:	18-06-2020
Actual enrolment:	2