A study of gevokizumab in subjects with Behçet s disease uveitis

Submission date	Recruitment status	Prospectively registered		
20/02/2012	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/04/2012	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
18/04/2018	Skin and Connective Tissue Diseases			

Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL2-78989-001 / X052096

Study information

Scientific Title

An open-label safety and pharmacokinetic study of gevokizumab in subjects with Behçets disease uveitis

Study objectives

To evaluate the safety of gevokizumab as well the drug concentration in the blood of patients with Behçets Disease Uveitis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Study design

International multicentre randomized open-label parallel group descriptive study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Behçets disease uveitis

Interventions

Three open treatment arms on top of stable background treatment for a one year period, with either:

Gevokizumab

- 1. Dose 1 intravenous (IV) followed by monthly dose 1 subcutaneous (SC), or
- 2. Dose 1 IV followed by dose 2 SC, or
- 3. Dose 2 IV followed by monthly dose 2 IV

In addition for patients with an acute ocular exacerbation at presentation, an IV injection is repeated 2 to 3 weeks later, before continuing monthly administrations

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gevokizumab

Primary outcome measure

Safety evaluation throughout the study

- 1. Adverse events
- 2. Vital signs
- 3. Laboratory values
- 4. Standard 12-lead electrocardiograms (ECGs) and chest X-ray at baseline and at study end

Secondary outcome measures

- 1. Pharmacokinetics from baseline until the study end (serum samples)
- 2. Ophthalmological assessments

Overall study start date

01/02/2012

Completion date

01/05/2013

Eligibility

Key inclusion criteria

- 1. Patients with uveitis associated with Behçet's disease diagnosis fulfilling the International Study Group Classification Criteria
- 2. Male or female, age [18 or legal age of majority-80] years old
- 3. Stable regimen of oral corticosteroids and at least one immunosuppressive treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

21

Key exclusion criteria

- 1. Infectious uveitis, uveitis due to causes other than Behçet's disease, or uveitis of unknown origin
- 2. Cataract so severe that an assessment of the posterior segment of the uvea and the fundus is

inadequate or impossible

3. History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies

Date of first enrolment

01/02/2012

Date of final enrolment

01/05/2013

Locations

Countries of recruitment

Korea, South

Tunisia

Türkiye

Study participating centre Istanbul University

Istanbul Türkiye 34390

Sponsor information

Organisation

Institut de Recherches Internationales Servier (France)

Sponsor details

50 rue Carnot Suresnes France 92284

Sponsor type

Industry

Website

http://www.servier.com/

ROR

https://ror.org/034e7c066

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan

Publication plan:

Summary results are published in https://clinicaltrials.servier.com.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No