

A study of gevokizumab in subjects with Behçet's disease uveitis

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

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

Prof Ahmet Gul

Contact details

Istanbul University
Istanbul Faculty of Medicine
Department of Internal Medicine
Division of Rheumatology
Istanbul
Türkiye
34390

Additional identifiers

Protocol serial number

CL2-78989-001 / X052096

Study information

Scientific Title

An open-label safety and pharmacokinetic study of gevokizumab in subjects with Behçet's 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

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