ISRCTN15180871 https://doi.org/10.1186/ISRCTN15180871

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

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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 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes