

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

<b>Submission date</b> 20/02/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/04/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/04/2018	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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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 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?
<a href="#">Basic results</a>				No	No