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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

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