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Pre and post vitrectomy infliximab in Bechet's disease posterior uveitis

Submission date 21/02/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/02/2017	**Overall study status** Completed	
Last Edited 29/01/2019	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Behçet's disease is a rare condition that results in inflammation of the blood vessels and tissues, including inflammation of the eyes. This study involves adult patients who have been diagnosed with Bechet's disease with eye inflammation that is not responding to treatments such as immunosuppressant drugs, and have eye complications that require surgery. The drug infliximab has been used to treat many conditions related to immune system disorders with promising results, but the drug is still not considered in routine treatment in many countries due to the high cost of the drug and the need for further doses for a long period to prevent the disease from coming back. In countries without medical insurance programs, doctors therefore face a problem treating patients with eye inflammation that is not responding to treatment. The aim of this study is to find out whether infliximab treatment before and after surgery reduces the possible risks of surgery on an inflamed eye, and results in a longer disease-free period (remission) even after stopping the drug.

Who can participate?
Patients aged 18-60 with Bechet's disease with severe eye inflammation and vision-threatening complications requiring surgery, and not responding to treatment, including immunosuppressants

What does the study involve?
All participants are treated with infliximab given directly into a vein, followed by an additional two cycles 2 weeks apart to give a total of three treatment cycles before the intended surgery, to be followed by another three cycles after surgery. The participants are followed-up for any disease activity for up to 6 months.

What are the possible benefits and risks of participating?
The participants may benefit from being treated with a highly effective and expensive medication that is not covered by their medical insurance in a completely free manner, with the possibility of reducing the daily doses of their current medications, reducing the impact of side effects. The risks are expected to be minimal, as they are related to infliximab side effects, which will be kept to a minimum through careful selection of participants and follow up.

Where is the study run from?
Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
February 2014 to January 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Heba El Gendy

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of pre and post operative infliximab in controlling Bechet's disease posterior uveitis in patients undergoing vitrectomy: a preliminary study

Study objectives
1. The pre-operative infliximab can control the ocular inflammatory condition and decrease the risk of intra-operative and post-operative complications
2. The continued post-operative infliximab can induce a long disease remission period

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local institutional ethics committee, 05/12/2013

Study design
Prospective non-controlled interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Bechet's disease posterior uveitis

Interventions
The drug infliximab was given in a dose of 5 mg/kg intravenous infusion over a three-hour period once every two weeks for 3 treatment sessions prior to the planned pars plana vitrectomy, after stoppage of other immunosuppressant drugs and keeping the patients on their pre-exposure daily doses of corticosteroids. All patients underwent vitrectomy operation, and vitreous opacities as well as epiretinal and retinal membranes were managed accordingly. The drug infliximab was then given in a dose of 5 mg/kg intravenous infusion once every two weeks for 3 treatment sessions after the surgical intervention. Patients were observed for 1 hour after stopping infusion for adverse effects. Infusions were followed by maintenance treatment of oral prednisone, that was tapered accordingly. No patients were treated with topical steroids, or retrobulbar steroid injections. All patients were followed up for a period up to 6 months following the last treatment cycle.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Infliximab

Primary outcome measure

The improvement of ocular inflammatory reaction in response to the drug used, monitored clinically (i.e. improvement in ocular pain, improvement of the visual acuity measured in Log MAR, improvement in anterior chamber flare and cells, improvement in vitreous cells), measured before the initiation of each new treatment cycle (every 2 weeks), as well as during the follow-up periods (monthly after stopping of the drug infliximab at the last session, for a 6-month period)

Secondary outcome measures
1. Reduction in concomitant corticosteroids requirements (average daily dose), as the doses are gradually tapered once improvement of ocular inflammatory reaction is achieved and continued reduction based on the patient’s response reaching the minimum daily dose sufficient to maintain quite eye with no active inflammatory reaction.
2. The occurrence of disease reactivation (relapses), where disease activity is defined as cells and flare in the anterior chamber, vitreous cells, retinal perivascular sheathing, retinal infiltration, new retinal hemorrhages or optic papillitis, monitored on a monthly basis after stopping of the drug infliximab for a total period of 6 months after the last treatment cycle

Overall study start date
01/02/2014

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1. Bechet's disease persistent posterior uveitis not responding to systemic treatment
2. Eyes with dense persistent vitreous opacities
3. Eyes with epiretinal membranes
4. Persistent macular edema
5. Age 18-60 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Patients with active infections
2. End-stage disease
3. Impaired liver function, leucopenia and thrombocytopenia
4. Patients receiving immunosuppressants other than corticosteroids at time of application of the drug

Date of first enrolment
01/02/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Egypt

Study participating centre
Cairo University
Faculty of Medicine
Egypt
11562

Sponsor information

Organisation
Cairo University

Sponsor details
Faculty of Medicine
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Sponsor type
University/education

Website
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ROR

https://ror.org/03q21mh05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
28/02/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017	29/01/2019	Yes	No