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Role of Atorvastatin for treatment of Central Retinal Vein Occlusion and long term prognosis

Submission date 08/05/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/07/2007	**Overall study status** Stopped	
Last Edited 15/12/2017	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ACRVOS

Study information

Scientific Title

Role of Atorvastatin for treatment of Central Retinal Vein Occlusion and long term prognosis

Acronym
ACRVOS (Atorvastatin for CRVO Study)

Study objectives
It has been suggested that in some instances an atherosclerotic central retinal artery impinges on the central vein, causing turbulence, endothelial damage and thrombus formation. Atorvastatin, with its lipid lowering action, may help in reducing the impingement on central retinal vein and therefore help in restoring the normal blood flow. Apart from the primary hypothesis, the protective role on endothelium may also be a determining factor for the final visual outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was not applied for since we don't have such a body here in India. Also, since the drug we plan to try is being prescribed for various other pathologies, this is just another indication which we might come up with.

This particular trial is the first one of the use of this drug for the given problem. There has not even been a case report of the drug use for CRVO. Since we have deeply studied the pathology of the disease and the action of the drug, we are expecting a positive response.

The patients will be fully informed of the nature of the treatment and only after consent will the drug be used.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Central Retinal Vein Occlusion

Interventions

Intervention treatment:
Duration of atorvastatin planned to be given is for two months. Dosage is to be 10 mg per day, given once in a day, orally.

Control treatment:
Treatment as usual.

Both groups will be subject to Laser pan-retinal photocoagulation and regular protocol in case of any complications arising from CRVO.

Follow up will be for every third/fourth day upto a maximum of 15 days from the date of incident and then once every week for a period of month. A late follow up is planned at six months from the incident of CRVO and at one year.

Patients who report to us within 24 hours of CRVO will receive the regular care and treatment so as to release/dissolve the clot and restore normal flow and such cases will obviously be not included in any group. Since this treatment is usually not effective after a few hours, we have planned our study for cases presenting at a late stage and for long term prognosis.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Visual acuity
2. Tortuosity of retinal veins

Secondary outcome measures
Recurrence of Central Retinal Vein Occlusion

Overall study start date
10/05/2007

Completion date
09/05/2009

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Patients with:
1. Central Retinal Vein Occlusion (CRVO) of more than one day duration
2. No other ophthalmic pathologies

3. No contraindication to atorvastatin
4. No prior use of statins

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
Patients with CRVO of less than one day duration are treated conventionally and those who have other ophthalmic pathologies or patients who have been on atorvastatin or any other statins earlier are not included in any groups.

Date of first enrolment
10/05/2007

Date of final enrolment
09/05/2009

Locations

Countries of recruitment
India

Study participating centre
3/198 Vishnupuri
Kanpur
India
208002

Sponsor information

Organisation
J L Rohatgi Eye Hospital (India)

Sponsor details
Sarvodaya Nagar
Kanpur

India
208002
-
jlrhospital@hotmail.com

Sponsor type
Hospital/treatment centre

Website
http://www.jlrohatgihospital.org/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
J L Rohatgi Memorial Eye Hospital (India) and investigator funded trial

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration