Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Treatment of macular edema secondary to central vein occlusion

Protocol summary

Summary

Eligible patients are submmitted to a complete ophthalmological examination. Fluorescein angiogram and Optical Coherence Tomograpy (OCT) will be performed at predetermined frequency. Patients will be submitted to intravitreal injections of 1.25 mg of bevacizumab every five weeks until OCT central macular thickness is bellow 250 microns up to a limit of 6 consecutive injections. After normalization of CMT, patients will be submitted to a single session of argon green laser. Follow-up will be performed at a 5-week interval. Main purpose is visual acuity and OCT changes. Improvement is defined as VA gain of 2 or more lines of ETDRS letters. VA worsening is defined as VA drop of 2 or more ETDRS lines.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011295270N1**
Registration date: **2010-12-01, 1389/09/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-01, 1389/09/10

Registrant information

Name
Arnaldo Bordon
Name of organization / entity
Banco de Olhos de Sorocaba
Country
Brazil
Phone
0055112127000
Email address
afbordon@terra.com.br

Recruitment status

Recruitment complete

Funding source

Self funding by the Banco de Olhos de Sorocaba (Sorocaba Eye Bank Hospital)

Expected recruitment start date

2010-10-01, 1389/07/09

Expected recruitment end date

2011-06-01, 1390/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment of macular edema secondary to central vein occlusion

Public title

Treatment of macular edema secondary to central vein occlusion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion crieria: Visual acuity equal or worse than 20/40 and equal or greater than 20/400; Minimum OCT central thickness of 250 microns Onset of central vein occlusion between three and 12 months. Visual acuity better than 20/40 on the other eye Exclusion criteria: neovascularization of the retina, optic disk, iris or angle. Uncontrolled glaucoma Intraocular surgery and/or injection of any medication in the past 3 months

Age

From **50 years** old to **100 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

1

Registry name
VEIN OCCLUSION STUDY

Secondary trial Id
035/2010

Registration date
2010-05-08, 1389/02/18

Ethics committees

1

Ethics committee

Name of ethics committee
Hospital Oftalmologico de Sorocaba Ethics Committee

Street address
Rua Nabeck Shiroma, 210

City
Sorocaba

Postal code
18360

Approval date
2010-08-03, 1389/05/12

Ethics committee reference number
035/2010

Health conditions studied

1

Description of health condition studied
central vein occlusion

ICD-10 code
H34.8

ICD-10 code description
Other retinal vascular occlusions

Primary outcomes

1

Description
change of visual acuity

Timepoint
6 months

Method of measurement
ETDRS chart

Secondary outcomes

1

Description
OCT (Optical Coherence Tomograpy) central macular thickness changes

Timepoint
6 months

Method of measurement
Stratus OCT

Intervention groups

1

Description
Intravitreal injections of 1.25 mg of bevacizumab every five weeks until OCT central macular thickness is bellow 250 microns up to a limit of 6 consecutive injections. After normalization of CMT, patients will be submitted to a single session of argon green laser; No control

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Oftalmologico de Sorocaba

Full name of responsible person
Suellen Fogaca

Street address
Rua Nabeck Shiroma, 210

City
Sorocaba

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Banco de Olhos de Sorocaba

Full name of responsible person
Edil Souza

Street address
Rua Nabeck Shiroma, 210

City
Sorocaba

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Banco de Olhos de Sorocaba

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Hospital Oftalmologico de Sorocaba

Full name of responsible person
Janaina CR de Souza

Position
fellow of the retina service

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Arnaldo F Bordon

Position
Head of the Retina and Vitreous Sector

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty