Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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Full name of responsible person
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Person responsible for scientific inquiries

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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