

Surgery to remove orbital bloody tumors through the conjunctiva by aid of a device that facilitates the procedure

Submission date 16/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/06/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Hemangioma is a benign tumor that is found to grow within the orbit. Most commonly located behind the eye globe, it can push the eye forward causing eye-bulging doctors call proptosis.

The tumor can be removed through surgery entering via the lower eyelid (transconjunctival orbitotomy) using cryotherapy. Cryotherapy uses imaging guidance, a needle-like applicator called a cryoprobe, and liquid nitrogen or argon gas to create intense cold to freeze and destroy diseased tissue, including cancer cells.

The aim of this study is to evaluate the safety and efficacy of cryo-assisted transconjunctival orbitotomy for the extraction of intraconal cavernous hemangiomas.

Who can participate?

Patients with intraconal cavernous hemangiomas

What does the study involve?

The transconjunctival approach will be used for cryo-assisted lesion extraction. Cases will be followed for six months after the surgery.

What are the possible benefits and risks of participating?

Benefits: excision of the orbital tumors, avoid compression of the optic nerve and avoid exposure keratitis

Risks: trauma to the optic nerve, trauma to the globe, rupture of the mass and inability to remove the tumor

Where is the study run from?

Mansoura ophthalmic center (Egypt)

When is the study starting and how long is it expected to run for?

April 2017 to September 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Abd El Ghafar, aiman_eg_123@yahoo.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Transconjunctival cryo-assisted extraction of intraconal cavernous hemangioma

Study objectives
is the transconjunctival cryo-assisted approach for excision of intraconal cavernous hemangioma is safe and effective?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/05/2017, Mansoura institutional review board (IRB) (Mansoura University Faculty of Medicine, Mansoura, Egypt; +20 (0)1092127930; IRB.MFM@hotmail.com), ref: R/17.05.26

Study design

Interventional non comparative single center case series

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Orbital intraconal cavernous hemangioma

Interventions

Excision of intraconal cavernous hemangiomas were performed through the transconjunctival approach assisted by the cryo-probe.

Patients enrolled were informed about the nature of surgery and benefits and possible complications of the procedure. they were admitted from May 2017 to August 2018 and followed for 6 months after surgery.

Intervention Type

Procedure/Surgery

Primary outcome measure

The success of the operation and complications measured using direct interview of patients after six months

Secondary outcome measures

None

Overall study start date

02/04/2017

Completion date

14/09/2018

Eligibility

Key inclusion criteria

Patients with intraconal cavernous hemangiomas

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

18

Key exclusion criteria

Intraconal, non-compressible, solid lesions that simulate cavernous hemangioma e.g. schwannoma, solitary neurofibroma, and fibrous histiocytoma

Date of first enrolment

14/05/2017

Date of final enrolment

14/08/2018

Locations

Countries of recruitment

Egypt

Study participating centre

Mansoura ophthalmic center

Gomhoria steet

Mansoura

Egypt

35516

Sponsor information

Organisation

Mansoura University

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://ophc.mans.edu.eg/>

ROR

<https://ror.org/01k8vtd75>

Funder(s)**Funder type**

Not defined

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

BMC ophthalmology journal.

Intention to publish date

15/05/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request