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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	[_] Prospectively registered [_] Protocol
Registration date 24/04/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/06/2020	**Condition category** Eye Diseases	[_] Individual participant data [_] 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?
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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
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Sponsor information

Organisation
Mansoura University

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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