

Sutureless band and chandelier-assisted laser retinopexy for scleral buckling

Submission date 07/11/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/11/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 09/11/2017	Condition category Eye Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Retinal detachment occurs when the thin lining at the back of the eye (retina) pulls away from the blood vessels that supply it with oxygen and nutrients. An operation is needed to reattach the retina, such as scleral buckling, which involves fine bands being stitched on to the outside white of the eye (the sclera). Laser or freezing treatment is used to close up the tear or hole between the retina and the wall of the eye. Despite the high success rate of scleral buckling for uncomplicated retinal detachment, the surgery is associated with complications related to the technique. Improving the technique of scleral buckling would maintain the high success rate while decreasing the complications. This could include the surgeon using a different lighting and viewing system, using bands instead of broad buckles, using a laser instead of freezing treatment, and not using scleral sutures (stitches). The aim of this study is to assess whether these changes in the standard scleral buckling technique maintain the high success rate while limiting complications.

Who can participate?

Patients with recent retinal detachment

What does the study involve?

All participants undergo the modified scleral buckling technique. Retinal attachment, vision and complications are assessed at 1, 3 and 6 months.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Alexandria University (Egypt)

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

November 2013 to November 2015

Who is funding the study?

Alexandria Faculty of Medicine, Alexandria University (Egypt)

Who is the main contact?
Dr Amir Gomaa

Contact information

Type(s)
Scientific

Contact name
Dr Amir Gomaa

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Additional identifiers

Protocol serial number
0302183

Study information

Scientific Title
Applying sutureless encircling # 41 band and trans-scleral chandelier-assisted laser retinopexy for scleral buckling procedure

Study objectives
A combination of sutureless band, laser, and chandelier illumination can successfully treat retinal detachment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee Faculty of Medicine, Alexandria University, 26/02/2014, IRB NO: 00007555-FWA NO: 00015712

Primary study design
Interventional

Study design
Single-center unmasked uncontrolled interventional study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rhegmatogenous retinal detachments

Interventions

A modified technique for scleral buckling which includes using sutureless encircling # 41 band and trans-scleral chandelier-assisted laser retinopexy. The technique involved 360 degree periotomy, hanging the 4 recti, sutureless fixation of band number 41, then inserting the chandelier light and using the wide angle viewing system and the diode laser for retinopexy followed by drainage of subretinal fluid if needed. The total duration of follow up is 6 month.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Retinal attachment, evaluated by fundus examination at 1, 3 and 6 months

Key secondary outcome(s)

1. Complications, evaluated by fundus examination at 1, 3 and 6 months
2. Visual acuity, measured by Snellen chart and converted to log Mar at baseline, 1, 3 and 6 months

Completion date

01/11/2015

Eligibility

Key inclusion criteria

Recent onset rhegmatogenous retinal detachment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Media opacity
2. Proliferative vitreoretinopathy
3. Giant retinal tear
4. Macular hole
5. Children
6. High myopes

Date of first enrolment

26/02/2014

Date of final enrolment

26/02/2015

Locations

Countries of recruitment

Egypt

Study participating centre

Alexandria University

Faculty of Medicine

Khartoum Square

Azarita

Alexandria

Egypt

21514

Sponsor information

Organisation

Alexandria University

ROR

<https://ror.org/00mzz1w90>

Funder(s)

Funder type

University/education

Funder Name

Alexandria Faculty of Medicine, Alexandria University

Alternative Name(s)

Alexandria University Faculty of Medicine

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Egypt

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Amir Gomaa. All participants' consent was obtained and anonymisation was maintained.

IPD sharing plan summary

Available on request