ISRCTN38727845 https://doi.org/10.1186/ISRCTN38727845

Sutureless band and chandelier-assisted laser retinopexy for scleral buckling

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

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Single-center unmasked uncontrolled interventional study

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 to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/11/2013

Completion date
01/11/2015

Eligibility

Key inclusion criteria
Recent onset rhegmatogenous retinal detachment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

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
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Sponsor information

Organisation
Alexandria University

Sponsor details
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Sponsor type
University/education

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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

Publication and dissemination plan
Planned publication in the Journal of Ophthalmology.

Intention to publish date
01/12/2018

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