

# Sutureless band and chandelier-assisted laser retinopexy for scleral buckling

<b>Submission date</b> 07/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/11/2017	<b>Condition category</b> 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

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

### ORCID ID

<https://orcid.org/0000-0002-3263-6957>

### Contact details

2 Sayadla Street, Smouha

Alexandria

Egypt

21615

## 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

### Study design

Single-center unmasked uncontrolled interventional study

### Primary study design

Interventional

### 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