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Releasable scleral buckling is recommend for phakic primary rhegmatogenous retinal detachment patients

Submission date
12/09/2017

Recruitment status
No longer recruiting

Registration date
04/10/2017

Overall study status
Completed

Last Edited
15/11/2023

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Rhegmatogenous retinal detachment (RRD) occurs when the fluid from the vitreous cavity (the part of the eye that has vitreous humour (fluid)) passes through a break and separates the outer segments of the retina and causes vitreous traction. The main treatments for an RRD are the pars plana vitrectomy (PPV) and scleral buckling (SB). The PPV technique directly relieves the vitreous traction directly by using the draining the fluid, gas-fluid exchange, and laser photocoagulation or cryotherapy of the reattached retina combined with or without a silicone oil tamponade. The SB technique is known to relieve the vitreous traction indirectly by using a segmental scleral silicone implant in the area corresponding to the retinal break and the encircling silicone band, combined with drainage of the subretinal fluid and transscleral cryotherapy. However, SB does have some complications, like axial elongation with secondary myopization, anterior-segment ischemia with the compression of the long posterior arteries, choroidal detachment and lens displacement with anterior chamber shallowing, and motility disturbances. In order to reduce the incidence of such complications, conventional SB procedure was modified and a new releasable scleral buckling (RSB) technique was designed. Instead of the silicone sleeves, absorbable sutures are used. There is still no consensus on the best approach for the management of uncomplicated RRD cases. The aim of this study is to determine whether the RSB procedure for patients with RRD is an effective approach.

Who can participate?
Adults aged 18 and older who have RRD.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the PPV treatment. Those in the second group receive the RSB treatment. Participants are assessed for their rate of retinal reattachment and their vision outcomes.

What are the possible benefits and risks of participating?
Participants may benefit from priority surgery and by getting subsidies for their trip. There are no risks with taking part of the study however there are risks with the PPV or RSB itself.

When is the study starting and how long is it expected to run for?
June 2017 to August 2019

Where is the study run from?
Zhongshan Ophthalmic Center (China)

Who is funding the study?
National Natural Science Foundation of China (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Ethics Committee of the Zhongshan Ophthalmic Center (2017KYPJ058)

Study information

Scientific Title
Comparison of Releasable Scleral Buckling and Vitrectomy in Phakic Primary Rhegmatogenous Retinal Detachment Patients

Study objectives
Releasable scleral buckling (RSB) is not worse than pars plana vitrectomy (PPV) in phakic patients with primary rhegmatogenous retinal detachment (RRD).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee of the Zhongshan Ophthalmic Center, 08/07/2017, ref: 2017KYPJ058

Study design
Prospective randomised clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary rhegmatogenous retinal detachment

Interventions
120 patients are randomly collected in a 1:1 ratio for treatments using RSB or PPV (n=60 in each cohort) from Zhongshan Ophthalmic Center. These patients were randomly picked up from the patients of RSB or PPV groups without any information except the names of interventions. The patients selectively received RSB or PPV following protocol.

In the RSB group, the episcleral encircling band (2.5×120mm) was episclerally fixed by 5-0 nonabsorbable sutures in the equatorial region of each quadrant. The ends of the encircling band were joined and preliminarily fixed by a silicone sleeve to adjust the strain of the encircling band. We tied up both ends using 6-0 absorbable sutures and removed the silicone sleeve. The retinal breaks were coagulated by retinal transscleral cryopexy. At the surgeon’s discretion, an additional segmental silicone buckle, if needed, was placed under the encircling band at the location of the retinal breaks. These additional segmental buckles were orientated parallel to the encircling band and were fixed on the sclera with additional sutures, independent of the encircling band. Other optional surgical steps included transscleral exodrainage of subretinal fluid and anterior chamber paracentesis.

In the PPV group, patients underwent standard 23-gauge (23G) vitrectomy while the vitreous was removed through to relieve all the tractions surround the retinal break. Drainage of the subretinal fluid was achieved through a preexisting break with or without perfluoro-N-octane assistance. Endolaser was used to surround all retinal breaks. All surgeries utilised an intraocular tamponade agent of 10% C3F8. 23G sclerotomy was sutured only if it leaked at the end of the surgery.

Participants are followed up at one day, one week, one month, three months, six months and 12 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Primary anatomical success rate is defined as the retina maintaining reattached after one operation at 12 months.

Key secondary outcome(s))
1. Best corrected visual acuity (BCVA) is measured using ETDRS chart converted to the logarithm of the minimum angle of resolution (logMAR) at 12 months
2. Cataract progression is determined by one doctor if considered to be visually significant at 12 months
3. Intraocular pressure (IOP) measured using a non-contact tonometer at one day, one week, one month, three months, six months and 12 months
4. Choroidal thickness (CT) is measured using enhanced depth-imaging spectral-domain optical coherence tomography (SD-OCT) imaging at subfovea (Spectralis; Heidelberg Engineering, Heidelberg, Germany) at one day, one week, one month, three months, six months and 12 months
5. Axial length (AL) is measured using the IOL Master (Carl Zeiss, Tubingen, Germany) at one month, three months, six months and 12 months
6. Complications is measured using slitlamp at one day, one week, one month, three months, six months and 12 months

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. Primary RRD without any complicating factors 14
2. Equal or older than 18 years old
3. Proliferative vitreoretinopathy (PVR) grade A or B

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
110

Key exclusion criteria
1. Patients with any kind of prior ocular surgery
2. Trauma
3. RD result from macular hole

4. RD with choroidal detachment detected by UBM15
5. Severe cataract
6. Prior posterior uveitis

Date of first enrolment
10/07/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
China

Study participating centre
Zhongshan Ophthalmic Center
No.54 Xianlie South Road
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Sponsor information

Organisation
Zhongshan Ophthalmic Center

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2020	15/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes