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Surgical treatment of retinal detachment with and without combined cataract extraction

Submission date	Recruitment status	[_] Prospectively registered
21/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2022	Eye Diseases	

Plain English summary of protocol

Background and study aims
Rhegmatogenous retinal detachment (RRD) is a potentially blinding eye disease resulting from the separation of the neurosensory retina from the retinal pigment epithelium because of formation of a retinal break and entry of fluid from the vitreous cavity to the subretinal space. RRD is largely more common in adults with myopia or an artificial lens, but it can affect younger patients, particularly those with risk factors such as eye trauma or hereditary abnormalities.

Parsplana vitrectomy (PPV) is nowadays the primary surgical procedure to obtain the repair of the RRD. For eyes that still have their natural lens, PPV can be performed with or without removing the lens, and previous studies have reported advantages and drawbacks for both approaches. The lens can be removed by phacoemulsification, a procedure in which an ultrasonic device is used to break up and then remove a cloudy lens. The aim of this study is to compare PPV with or without phacoemulsification in terms of anatomical success and functional outcomes.

Who can participate?
Patients aged 48 - 65 years scheduled for vitreoretinal surgery to treat RRDto treat rhegmatogenous retinal detachment (RRD).

What does the study involve?
Patients scheduled for vitreoretinal surgery to treat a recent RRD, after a full ophthalmological evaluation, receive PPV with or without phacoemulsification. The patients are then asked to undergo postoperative eyedrop therapy and follow up with complete visits at 1 week, 1, 3 and 6 months after the PPV procedure.

What are the possible benefits and risks of participating?
Benefits of PPV with phacoemulsification might be better visualization and access during surgery and therefore a reduced need for a second surgery. However, there are also disadvantages as there is a risk of postoperative visual errors such as blurred vision and uneven focussing between the two eyes, and can lead to the removal of a largely healthy organ in cases of no/mild cataract.

Where is the study run from?
University Hospital of Parma (Italy)

When is the study starting and how long is it expected to run for?
December 2017 to December 2021

Who is funding the study?
Università degli Studi di Parma (Italy)

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
569/2018

Study information

Scientific Title
Parsplana vitrectomy alone versus parsplana vitrectomy combined with phacoemulsification for the treatment of rhegmatogenous retinal detachment: a randomized study

Study objectives
To compare the anatomical success rate, defined as retinal reattachment 6 months after primary surgery without reoperation between parsplana vitrectomy alone versus parsplana vitrectomy combined with phacoemulsification.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2018, Comitato Etico dell'Area Vasta Emilia Nord– Sede Locale Di Parma (Segreteria Locale di Parma, Via Gramsci 14 – 43126 Parma, Italy; +39.0521 703013/703608; comitatoetico@ao.pr.it), ref: 569/2018

Study design
Hospital-based, prospective randomized study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, written in Italian (please use contact details to request a participant information sheet)

Health condition(s) or problem(s) studied
Rhegmatogenous retinal detachment treated by parsplana vitrectomy (PPV)

Interventions
Group A: Lens-sparing technique (PPV-only)
Group B: Phacovitrectomy
Postoperative follow up: 6 months

The method of randomisation was "equal simple randomisation".
Group A: Lens-sparing technique (PPV-only). PPV will be performed using a binocular indirect ophthalmomicroscope (BIOM; Oculus, Wetzlar, Germany) for noncontact, wide-angle surgery. A 25-gauge trocar with a valved cannula will be inserted transconjunctivally in the inferotemporal, superotemporal, and superonasal quadrants, 4 mm posterior to the limbus. During the procedure, core vitrectomy is initially performed. When the posterior hyaloid is attached to the posterior pole, detachment will be performed using the vitreous probe at an aspiration rate of 400 mmHg. Perfluorocarbon liquid (PFCL) will be injected intravitreally up to around 2 disc diameters from the posterior edge of the less peripheral tear, to promote internal subretinal fluid drainage during fluid-air exchange. Cryopexy will be used to freeze areas around the retinal

breaks and those adjacent to the sclerotomies. Fluid–air exchange will be performed to remove all balanced saline solution and PFCL before gas tamponade (C3F8 at 18%). At the end of surgery, all trocars are removed and sutures placed according to the watertight nature of the holes. A subconjunctival injection of 0.2 mL of gentamicin and dexamethasone solution will be administered before the lid speculum is removed.

Group B: Phacovitrectomy. Standard phacoemulsification will be performed systematically before the PPV through a 2.2-mm clear corneal incision, with implantation of a hydrophobic, acrylic, foldable monofocal IOL. The subsequent vitrectomy procedure is the same as that mentioned above, except that argon endolaser treatment of the breaks is used instead of cryopexy.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Anatomical success rate, defined as retinal reattachment 6 months after primary surgery without reoperation (postoperative argon laser treatment on areas considered to be at risk for new rhegmatogenous events was not considered as reoperation), measured using fundoscopy at 1, 3, and 6 months

Secondary outcome measures
1. Final best-corrected visual acuity (BCVA) measured using the Early Treatment Diabetic Retinopathy Study chart at 4 meters at 1, 3, and 6 months
2. Intraocular pressure (IOP) (in mmHg) measured using the Goldmann applanation tonometry at 1, 3, and 6 months
3. Central macular thickness (CMT) (in micrometers) measured using on Optical Coherence Tomography scan at 1, 3, and 6 months
4. Progression of the cataract (group A only) measured using the LOCS III scale at 1, 3, and 6 months

Overall study start date
01/12/2017

Completion date
01/07/2022

Eligibility

Key inclusion criteria
1. Aged 48–65 years with RRD in phakic eyes
2. The presence of up to three separate retinal tears within the superior 180° of the retinal circumference with an overall extension of retinal breaks <90°
3. Proliferative vitreoretinopathy (PVR) not exceeding the grade B according to the updated classification of 1991
4. Lens opacity not exceeding the first grade of each category of the Lens Opacities Classification System III (LOCS III) scale

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
By accepting a type I error of 5% and a type II error of 20% (i.e. a study power of 80%), a total sample size of 50 units (2 groups of 25 units) was required

Total final enrolment
64

Key exclusion criteria
1. Previous surgery in the affected eye (excluding corneal refractive procedures)
2. Current use of topical hypotensive medications
3. Documented diabetic or hypertensive retinopathy
4. Age-related maculopathy
5. Optic nerve vascular pathologies

Date of first enrolment
01/12/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Italy

Study participating centre
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University/education

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Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Parma

Alternative Name(s)
Università di Parma, University of Parma, UNIPR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Publication and dissemination plan

A publication of the ad interim results and of the full data is planned in a high-impact peer-reviewed journal. The protocol is stored up in online and paper version by the Local Ethics Committee. Referring to a monocentric local study the protocol is written in Italian.

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
For access to the dataset please contact Paolo Mora, email: paolo.mora@unipr.it and/or Lucia Benatti email: lucia.benatti.90@gmail.com. The results of each follow up visit is reported in the medical chart and then entered in the Excel database available in a computer file accessible for the two people mentioned above. Once anonymized (only initials) data will be shared with the statistician for statistical analyses. Signed informed consents are preserved in a binder in the office of the PI (PM).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/05/2021	05/05/2021	Yes	No