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Intraocular injection of 0.3 ml C3F8 gas for the treatment of patients with vitreomacular traction

Submission date
06/09/2017

Recruitment status
No longer recruiting

Registration date
04/10/2017

Overall study status
Completed

Last Edited
13/09/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Vitreomacular traction (VMT) is disease of the macula (the small center of the retina that is the centre of our field of vision) causing reduced vision and distortion. The managment options for VMT include pars plana vitrectomy (a procedure that involves removal the gel from the eye), enzymatic vitreolysis (a technique that uses lasers to disrupt floaters) observation. Participants may have to undergo surgery to treat VMT. Intravitreal injections of a C3F8 gas (injections into the vitreal area of the eye) might avoid surgery. The aim of this study is to investigate if pneumatic vitreolysis with intravitreal injection of 0.3ml of 100% C3F8 gas can be a cost-effective and easy alternative to release the vitreomacular traction.

Who can participate?
Adults aged 18 and older who have symptomatic vitreomacular traction.

What does the study involve?
Participants receive the procedure which includes an injection into the eye with the 0.3ml of 100% C3F8 gas. They are asked not to lie flat on the back for five days. Participants are instructed to use eyedrops three times a day for three days. Participants are followed up the next day, one week and four weeks after surgery. If the treatment was successful the participants are referred back to the private ophthalmologist (eye surgeon). If the treatment wasn’t successful further treatment is offered.

What are the possible benefits and risks of participating?
Participants may benefit from having this procedure instead of having surgery. There is risks associated with an intravitreal injections including pain, bleeding, retinal tears, infections, loss of vision, loss of eyes (from severe injections), and need for further surgery.

Where is the study run from?
Eye Clinic, Cantonal Hospital Sankt Gallen (Switzerland)

When is the study starting and how long is it expected to run for?
September 2017 to March 2018

Who is funding the study?
Investigator initiated and funded (Switzerland)

Who is the main contact?
Dr Josef Guber

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
C3F8VMT

Study information

Scientific Title
Outcome after gas injection for the treatment of vitreomacular traction

Study objectives
Intravitreal injection of 100% 0.3ml C3F8 Gas would release the vitreomacular traction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional prospective study pre-post study design single center

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with symptomatic vitreomacular traction

Interventions
Patients with symptomatic vitreomacular traction are included in this study. This procedure is performed by an experienced surgeon. The intervention takes about 10 minutes.

Injection Technique:
At the beginning a time-out is performed to confirm correct medication and correct eye. The participant is placed in near supine position. The procedure is performed in topical anesthesia only using lidocaine eyedrops. The eye and the eyelids are cleaned with Betadine and a drape is used to cover the face. An eyelid speculum holds the eye open. The location of injection is marked using an caliper: 3-3.5mm from the limbus for pseudophakes, 3.5-4.0 mm for phakic patients. The injection is performed with a short 30g needle tip usually in the superotemporal quadrant. At the end of surgery topical antibiotic is administer into the eye.

Medication:
Participants have 0.3ml of C3F8 gas injected into the eye.
Participants are asked not to lie flat on the back for five days. A topical therapy with tobramycin eyedrops 3 times for three days is prescribed.

Participants are reviewed next day, after a week and after four weeks postoperatively. Each participant receive a complete ophthalmological examination including best-corrected visual acuity and spectral domain optical coherence tomography (SD-OCT) (Spectralis HRA OCT, Heidelberg Engineering, Heidelberg, Germany) prior to surgery as well as one week and four weeks after surgery respectively.

Intervention Type
Mixed

Primary outcome(s)
Release of vitreomacular traction will be checked by using an optical coherence tomography at one week and four weeks postoperatively.

Key secondary outcome(s))
Visual acuity and central retinal thickness is measured using a Snellen chart and an optical coherence tomography at one and four weeks postoperatively.

Completion date
01/03/2020

Eligibility

Key inclusion criteria

1. All patients with a symptomatic vitreomacular traction
2. Aged 18 and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
26

Key exclusion criteria
1. Presence of Epiretinal Membrane over the macula at baseline
2. Broad VMT/VMA >1500 microns at baseline
3. History of vitrectomy/injections
4. History of laser photocoagulation to the macula in the study eye
5. High myopia
6. Aphakia
7. History of retinal detachment/breaks/Vitreous hemorrhage
8. Diabetic retinopathy, ischaemic retinopathies, retinal vein occlusio

Date of first enrolment
01/10/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Eye Clinic, Cantonal Hospital Sankt Gallen
Sankt Gallen
Switzerland
9006

Sponsor information

Organisation
Kantonsspital St.Gallen

ROR
https://ror.org/00gpmb873

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/09/2021	13/09/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes