

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/09/2021	Condition category Eye Diseases	<input type="checkbox"/> 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 management 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
Dr Josef Guber

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 a 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 administered 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 receives 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 measure

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

Secondary outcome measures

Visual acuity and central retinal thickness is measured using a Snellen chart and an optical coherence tomography at one and four weeks postoperatively.

Overall study start date

01/09/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

12

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 occlusion

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

Sponsor details

Haus 04

Rorschacher Strasse 95

St.Gallen

Switzerland

9007

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00gpmb873>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/03/2021

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