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

Submission date 06/09/2017	<b>Recruitment status</b> No longer recruiting	<pre>[] Prospective [] Protocol</pre>
<b>Registration date</b> 04/10/2017	<b>Overall study status</b> Completed	<ul> <li>Statistical a</li> <li>[X] Results</li> </ul>
Last Edited 13/09/2021	<b>Condition category</b> Eye Diseases	[_] Individual p

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## 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 costeffective 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

ORCID ID http://orcid.org/0000-0003-2681-4961

**Contact details** Kantonsspital St.Gallen Rorschacher Strasse 95 Haus 04 Sankt Gallen Switzerland 9007

## 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 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 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 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

**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