

# Does silicone oil change ocular temperature?

<b>Submission date</b> 19/01/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/02/2017	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Eyes contain a jelly-like liquid called vitreous. When a patient is having surgery on their retina (the part of the eye where light signals are sent to the brain to create an image) this liquid has to be removed in order to gain access. This surgical procedure is known as a pars plana vitrectomy. During this procedure, vitreous needs to be replaced with a saline (salt water). In some cases, the retina can become detached from the eye and so silicone oil tamponade (gel) may be used to keep the retina in place. Silicone oil carries heat differently to water and these heat changes can lead to blurred vision. This study aims to compare eye temperature in participants who have an eye with silicone oil tamponade and an eye without it, in order to determine if silicone oil affects the temperature.

### Who can participate?

Adults who are having a pars plana vitrectomy using silicone oil tamponade as part of their normal care.

### What does the study involve?

The temperature of each participant's cornea (the out layer of the eye) is measured using a handheld non-contact thermometer in both eyes. This involves shining a special light into the eye which measures the temperature. Three temperature readings from each eye are taken. Participants also have their overall body temperature (taken from their forehead) measured using the same method.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks to those taking part in the study.

### Where is the study run from?

Istanbul Education and Research Hospital (Turkey)

### When is the study starting and how long is it expected to run for?

November 2015 to May 2016

### Who is funding the study?

Investigator initiated and funded (Turkey)

Who is the main contact?

Dr. Erkan Unsal

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## Contact information

### Type(s)

Public

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Temperature effect of silicone oil at the anterior segment

### Study objectives

The aim of this study is to measure the temperature difference between eyes with and without silicone oil tamponade.

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

Ethical Review Board of Istanbul Education and Research Hospital, 20/11/2015, ref: 2015-728

**Study design**

Observational single-centre cross-sectional study

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use the contact details below to request a participant information sheet

**Health condition(s) or problem(s) studied**

Pars plana vitrectomy, intraocular silicone oil tamponade

**Interventions**

Participants have their central corneal eye temperature and their body temperature measured in a room with fixed temperature, humidity and illumination. To avoid inter-observer variations, all temperature measurements is done by a single examiner in the same examination room.

Central corneal temperatures are measured using a non-contact infrared thermometer from the corneal surface. The aiming beam of handheld infrared skin thermometer is centered slightly inferotemporally to the center of cornea. The working distance is the distance where the aiming beam formed a sharp concentric rings on the iris. Three measurements from each eye are taken and mean value for each eye is used for analysis.

Body temperature is measured using a non-contact infrared thermometer taken from the forehead. This device measures body temperature from 16 °C to 40 °C with a minimum accuracy of 0.2 °C. Measurements are obtained in less than one seconds in each patient.

**Intervention Type**

Other

**Primary outcome measure**

1. Corneal eye temperature both with and without silicone oil is measured using with noncontact infrared thermometer on the study visit
2. Body temperature is measured using a noncontact infrared thermometer on the study visit

**Secondary outcome measures**

No secondary outcome measures.

**Overall study start date**

20/11/2015

**Completion date**

01/09/2016

## Eligibility

**Key inclusion criteria**

1. Require a pars plana vitrectomy and intraocular silicone oil tamponade
2. Aged between 36-88

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

38 Male / 22 Female

**Key exclusion criteria**

1. Active ocular or periocular infection
2. Systemic infective illnesses

**Date of first enrolment**

01/12/2015

**Date of final enrolment**

30/05/2016

## Locations

**Countries of recruitment**

Türkiye

**Study participating centre**

**Istanbul Education and Research Hospital**

Department of Ophthalmology

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# Sponsor information

## Organisation

Istanbul Research and Training Hospital

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/00nwc4v84>

# Funder(s)

## Funder type

Not defined

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration.

## Intention to publish date

01/09/2017

## 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