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Does silicone oil change ocular temperature?

Submission date
19/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
09/02/2017

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 plars 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?
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Contact information

Type(s)
Public

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Additional identifiers

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

Primary study design
Observational

Study design
Observational single-centre cross-sectional study

Study type(s)
Screening

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(s)
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

Key secondary outcome(s)
No secondary outcome measures.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Istanbul Research and Training Hospital

ROR
https://ror.org/00nwc4v84

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

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