

Changes in pupil size following phacoemulsification surgery

Submission date 07/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/06/2015	Condition category 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

The aim of this study is to detect the changes in pupil size following cataract surgery.

Who can participate?

Adults aged 48 to 81 and undergoing cataract surgery.

What does the study involve?

All patients will receive the same type of intraocular lens. Measurements will be made five minutes after the operation and then one month after the operation.

What are the possible benefits and risks of participating?

The benefit is better visual acuity after the operation. The risk is complication after standard cataract surgery.

Where is the study run from?

Uskudar University, Istanbul (Turkey).

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

From December 2014 to February 2015

Who is funding the study?

Uskudar University and GMMA Haydarpasa Training Hospital

Who is the main contact?

Dr. Yildiray Yildirim
yyildirim@gata.edu.tr

Contact information

Type(s)

Scientific

Contact name

Dr. Yildiray Yildirim

Contact details

GMMA Haydarpasa Training Hospital, Department of Ophthalmology
Istanbul
Türkiye
34000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information**Scientific Title**

Changes in pupil size following phacoemulsification surgery: a prospective cohort study

Study objectives

The pupil size is important in appropriate cases in whom the combination with phacoemulsification and multifocal intra ocular lenses (IOL) implantation would be performed. This is because postoperative visual disturbances may be directly related to the pupil size. Therefore, pupil size assessment of the patients who are to undergo implantation of a multifocal lens is important.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Research Ethics Committee of Haydarpasa Numune Training and Research Hospital, Istanbul. 22/12/2014, HNEAH-KAEK 2014/92

Study design

Prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Changes in pupil size developing after phacoemulsification surgery

Interventions

All patients will have phacoemulsification surgery and implantation of the same type of intraocular lens. Pupil measurements will be made after each patient waited in a dark room for 5 minutes preoperatively and will be repeated one month after the operation.

Intervention Type

Procedure/Surgery

Primary outcome measure

Preoperative and postoperative pupil size changes

Secondary outcome measures

Optic aberrations

Overall study start date

25/12/2014

Completion date

05/02/2015

Eligibility**Key inclusion criteria**

- 1- Male and female patients aged between 48 and 81
- 2- Patients with cataracts

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

49 patients

Key exclusion criteria

- 1- Patients who have a history of ocular trauma, uveitis, optic neuropathy or anisocoria and also have other accompanying serious ocular diseases except cataract
- 2- Patients who have a complicated phacoemulsification surgery

Date of first enrolment

25/12/2014

Date of final enrolment

05/01/2015

Locations

Countries of recruitment

Türkiye

Study participating centre

Uskudar University

Istanbul

Türkiye

34000

Study participating centre

GMMA Haydarpasa Training Hospital

Istanbul

Türkiye

34000

Sponsor information

Organisation

Uskudar University

Sponsor details

Altunizade District Haluk Turksoy Street. No:14

Istanbul

Türkiye

34662

+90 216 400 22 22

info@uskudar.edu.tr

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02dzjmc73>

Funder(s)

Funder type

University/education

Funder Name

Uskudar University

Results and Publications

Publication and dissemination plan

Publication of study results in peer-reviewed journal in 2015.

Intention to publish date

31/03/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request