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Changes in pupil size following phacoemulsification surgery

Submission date	Recruitment status	[ ] Prospectively registered
07/02/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/06/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/06/2015	Eye Diseases	[ ] 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, Istambul (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?
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Contact information

Type(s)
Scientific

Contact name
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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 occular 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
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Sponsor information

Organisation
Uskudar University

Sponsor details
Altunizade District Haluk Turksoy Street. No:14
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34662
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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