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Effect of phacoemulsification on trabeculectomy function

Submission date
30/05/2017

Recruitment status
No longer recruiting

Registration date
06/06/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cataracts occur when the inner lens of the eye clouds, causing vision problems. Glaucoma (high pressure inside the eye) can also cause vision problems. Cataracts can occur alongside glaucoma but also may cause glaucoma, be a result of glaucoma (high pressure inside the eye). For those who have glaucoma and cataracts, there are a number of options on how to treat them. Trabeculectomy is usually done to help lower the internal pressure of the eye by making a surgical incision through a small thin trap door in the eye to drain the fluid. However, this may have an impact on cataract surgery and requires certain management of treatment and medication. One of the main treatments for cataracts is called phacoemulsification, which is a surgical procedure that using a device to break up the cloud lens, and then inserts an intraocular lens (IOL) (an artificial lens) using an incision. Incisions can be made in different locations. The aim of this study is to compare two different corneal (the front clear layer of the eye) incisions of uneventful phacoemulsification and IOL on eyes that have undergone previous successful surgery for glaucoma.

Who can participate?
Adults aged 18 or older who previously had a success trabeculectomy for glaucoma who need cataract surgery

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo phacoemulsification with a temporal (near the front) corneal incision. Those in the second group undergo phacoemulsification with a superior corneal incision (done under the eye lid). Participants in each group are compared for their intraocular pressure changes (pressure in the eye), any blebs (part of the eye ballooning and protruding from the top of the eyeball) and any needed medication for glaucoma.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in vision. There are small risks associated with phacoemulsification such as infections, retinal detachment, flashing, double vision or swelling in the eye.

Where is the study run from?
Sohag University (Egypt)

When is the study starting and how long is it expected to run for?
October 2014 to January 2016.

Who is funding the study?
Investigator initiated and funded (Egypt)

Who is the main contact?
Dr Mohamed Anbar

Contact information

Type(s)
Scientific

Contact name
Dr Mohamed Anbar

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BOPH-D-16-00308R2

Study information

Scientific Title
Effect of different incision sites of phacoemulsification on trabeculectomy bleb function: Prospective case-control study

Study objectives
The aim of this study was to compare superior and temporal clear corneal incisions of uneventful phacoemulsification and in-the-bag intraocular lens implantation on intraocular pressure control and the bleb morphology in eyes that have undergone previous successful trabeculectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Prospective single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cataract and glaucoma

Interventions
Participants who previously undergone trabeculectomy without antimetabolites are consecutively allocated (1:1) to one of two groups.

Group 1 (Temporal group): Participants in this group undergo phacoemulsification with a temporal corneal incision.

Group 2 (Superior group): Participants in this group undergo phacoemulsification with a superior corneal incision.

Comparisons between the two groups are performed after one year of follow-up regarding intraocular pressure changes, bleb morphology score using the Wuerzburg bleb classification score and any added glaucoma medications.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Intraocular pressure changes is measured using the Goldman tonometer … at day one, one week, one month, three months, six months, and one year postoperatively
2. Bleb morphology score is measured using the Wuerzburg bleb classification score at day one, one week, one month, three months, six months, and one year postoperatively
3. Additional glaucoma medications are measured using patient's records up to one year postoperatively

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
15/10/2014

Completion date
15/01/2016

Eligibility

Key inclusion criteria
1. Previous successful trabeculectomy not augmented by antimetabolites and had well-controlled IOP
2. Well-functioning bleb, no preoperative glaucoma medications
3. A visually significant cataract before phacoemulsification
4. Aged 18 and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Patients with primary angle closure glaucoma,
2. Secondary glaucoma
3. Associated eye diseases
4. Preoperative antimetabolite use
5. Posterior capsule rupture and/or vitreous loss during phacoemulsification

Date of first enrolment
15/12/2014

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
Egypt

Study participating centre
Sohag University Hospital
Sohag University
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002

Sponsor information

Organisation
Sohag University

Sponsor details
Sohag University Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02wgx3e98

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication and dissemination plan and intention to publish date planned publication in a high-impact peer reviewed journal.

Intention to publish date
15/01/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (manber2006@yahoo.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/06/2017	26/11/2020	Yes	No