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Which of these two agents, Mitomycin C and Ologen™, is better to use when used in surgeries to treat cataract and glaucoma at the same time?

Submission date
23/11/2018

Recruitment status
No longer recruiting

Registration date
29/11/2018

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Cataract is a disease where the natural lens of the eye becomes opaque instead of clear. It has many causes, but mostly occurs as part of aging. It requires a surgery to replace the opaque natural lens with a clear artificial one. Glaucoma is a disease where the fluids inside the eyes are entrapped. This will raise the pressure inside the eye and will gradually damage the eye nerve, responsible for image transmission to the brain. The damage is gradual but permanent. If the eye pressure is not controlled, it might eventually lead to complete blindness. There are different types of glaucomas, depending on the cause and the location of fluid entrapment. If the cause is unknown, it is called primary. If the location is just outside the eye, and the structure is apparently normal, it is called open angle. Primary open angle glaucoma is one of the most common and serious causes of blindness in the modern world. To treat glaucoma you need to stop the damage of the nerve by controlling the pressure. Eye pressure control is first tried by medications, in the form of eye drops. One or more (up to 3) types of drops could be used for pressure control. However, surgery might be used to obtain the same results if the pressure is still not under control after using the maximum number of drugs. The simple idea of the surgery is to create a path for the entrapped fluid to exit the eye at an acceptable rate (not too slow, not too fast). This can be made by a "trap-door" that exits under the fine membrane covering the white of the eye (called conjunctiva). The conjunctiva might try to heal and return to its original status. This will cause fibrosis and closure of the trap-door, ending in failure of the surgery. There are several ways to prevent fibrosis. The most famous way is to use a medication called mitomycin-C (MMC), originally used in cancer, which prevent fibrosis. Another method is to preserve the space over the trap-door by placing a special type of medically prepared sponge (OlogenTM), which takes 6 months to dissolve. During these 6 months, the healing will complete and fibrosis will stop. It will leave a space "reservoir", where entrapped fluids can find their way out. Each of the methods has its own advantages and disadvantages (failure and complications). Both diseases, cataract and glaucoma, might occur in the same individual. The aim of this study is to find out which treatment is better to use, MMC or OlogenTM, in surgeries to treat cataract and glaucoma at the same time.

Who can participate?
Patients with cataract and primary open angle glaucoma not controlled by medical treatment

What does the study involve?
In this study, patients have a combined surgery for cataract and glaucoma. One third of the patients have the glaucoma surgery with MMC. One third of the patients have surgery with OlogenTM. Another third have the glaucoma surgery with both methods but with half the dose of MMC. Eye pressure control is assessed before surgery and 1 day, 1 week , 1, 3, 6, 9 and 12 months after surgery.

What are the possible benefits and risks of participating?
The possible benefit of participating is complete cure of both cataract and glaucoma. The possible risk is the occurrence of complications during or after the surgery as an example but not limited to: infection, failure to control eye pressure, or bleeding. These complications have the same chance of occurring as having the same surgery outside of the trial.

Where is the study run from?
1. Magrabi Eye Hospital (Egypt)
2. The Eye Consultants Center (Saudi Arabia)

When is the study starting and how long is it expected to run for?
November 2013 to March 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Momen Hamdi
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
002-13

Study information

Scientific Title
The role of Mitomycin C and Ologen™ in phacotrabeculectomy

Acronym
MMC and OlogenTM in Phacotrabe

Study objectives
Using both MMC and Ologen™ avoids complications of both and improves results in phacotrabeculectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Magrabi Eye Hospital, Cairo, Egypt, 24/9/2013 (no reference number available)
2. The Eye Consultants Center, Jeddah, Saudi Arabia, 11/11/2013 (no reference number available)

Study design
Prospective interventional comparative study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Surgical treatment for concomitant cataract and glaucoma

Interventions
Patients suffering from concomitant visually significant cataract and medically uncontrolled glaucoma, will undergo a combined procedure: cataract extraction and intraocular lens implantation (phacoemulsification and IOL) + glaucoma filtration surgery (trabeculectomy). The procedure is collectively known as "Phacotrabe". Phaco surgery is standard, while Trabe can be enhanced by various agents. The first agent is Mitomycin C: a drug used in treatment of tumors, that prevents cell replication. It prevents fibrosis of tissue that lead to failure of the surgery. Ologen™ is a biodegradable sponge. It is applied at the outlet of the path created by the surgery. It maintains the space for about 6 months, until the fibrosis procedure completes, sparing the area of the sponge and maintaining an open path.

Patients will be divided into three groups equally. Patients will be recruited consecutively, according to timing of surgery, into the three groups. All will receive phaco procedure. The first group will undergo trabe using full dose MMC (0.2 mg/ml for 3 min). The second group will undergo trabe with Ologen™. The third group will undergo trabe with Ologen™ + low dose MMC (0.2 mg/ml for 90 sec).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Intraocular pressure (IOP) control after surgery assessed using Goldman Tonometer at every examination: preoperative and postoperative 1 day, 1 week , 1, 3, 6, 9 and 12 months

Key secondary outcome(s))
1. Complications will be assessed during post-operative slit lamp examination after surgery at day 1, week 1 and month 1. These complications are: Hypotony (IOP <6 mmHg), shallow anterior chamber (iris and cornea touching) and significant hyphaema (bleeding inside the front part of the eye)
2. Number of postoperative medications needed to lower IOP, success in IOP control and the presence of blood vessels at site of surgery (bleb vascularity) will be assessed at 12 months:
2.1. Number of postoperative medications needed to lower IOP is assessed as follows: the use of one medication entails use of B-blockers eye drops twice a day. The use of two medications means combination of B-Blockers and Dorzolamide eye drops, twice a day. Three medications means the addition of Latanoprost eye drops, once at night time to the previous 2 medications
2.2. Success of IOP control is considered to be “Complete” with IOP < 21 mmHg without any additional topical medication. “Qualified” success considered with IOP < 21 mmHg with additional topical medication. “Failure” is considered with IOP > 21 mmHg despite maximum medications
2.3. The presence of blood vessels at site of surgery is detected by slit lamp examination and is graded by a five scaling score, where: Grade 0: no vessels at site of surgery. Grade 1: no vessels are present but there are small cysts and tissues are clear. Grade 2: few vessels are present (similar to adjacent tissues). Grade 3: moderate number of vessels. Grade 4: too many vessels

Completion date
31/03/2017

Eligibility

Key inclusion criteria
Patients having clinically significant cataract affecting best corrected visual acuity (BCVA) worse than 6/24 on Snellen's chart, together with Primary Open Angle Glaucoma (POAG) where IOP was not controlled by medical treatment (more than 21 mmHg despite maximally tolerated medications).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Other eye diseases (e.g. cornea, retina, etc)
2. Other forms of glaucoma than POAG (e.g. angle closure glaucoma, secondary glaucoma and congenital glaucoma)
3. Previous procedure for treatment of glaucoma (laser or previous surgery)

Date of first enrolment
18/12/2013

Date of final enrolment
20/03/2016

Locations

Countries of recruitment
Egypt

Saudi Arabia

Study participating centre
Magrabi Eye Hospital
Al Sayeda Nafisa, El Khalifa, El-Sayeda Zainab
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Study participating centre
The Eye Consultants Center
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Sponsor information

Organisation
Magrabi Eye Hospital

Organisation
The Eye Consultants Center

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Momen Hamdi (Mo2_76@hotmail.com). Data would be preserved for 3 years after publishing the results and available for inquiries. As per the signed informed consent signed before participation and according to the approval of ethical committees, only clinical data (like vision and IOP levels) of relevance can be released. Personal data that can identify participants like names and addresses will not be released.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2021	28/10/2022	Yes	No