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Comparing laser treatment to brimonidine /timolol eye drops in patients with primary open angle glaucoma.

Submission date
05/12/2018

Recruitment status
No longer recruiting

Registration date
14/12/2018

Overall study status
Completed

Last Edited
28/09/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Primary open angle glaucoma involves an increase of pressure inside the eye (intraocular pressure, IOP) that can cause damage to the optic nerve. Left untreated, glaucoma can lead to permanent and irreversible vision loss. Lowering IOP is currently the only way of controlling glaucoma. Glaucoma affects 2.7 million people in the United States and is expected to increase to 6.3 million people by 2050 therefore effective treatments are needed to manage the disease. Selective Laser Trabeculoplasty (SLT) works by unblocking drainage channels in the eye to allow more fluid to drain from the eye and lowering the intraocular pressure. One of SLT's main advantages is that it helps to lower intraocular pressure without the need for the patient to remember to put in eye drops each day .
The purpose of this study is to compare SLT to Combigan eye drops in lowering intraocular pressure as an additional treatment in in patients with primary open angle glaucoma whose IOP is not reduced enough using eye drops containing a prostaglandin-based drug alone.

Who can participate?
Male and female patients with primary open angle glaucoma who are aged 25-90 years old. Participants to one of two treatment groups and either receive additional drops or a laser procedure.

What does the study involve?
Participants will have an examination before the treatment starts to check blood pressure, pulse, visual acuity (how well they can read letters on a chart), pupils, eye movement muscles, intraocular pressure, and external eye health. The investigators will also assess how fluid drains from the eye using a procedure called gonioscopy and measure the thickness of the corneas. The baseline exam may last 1-2 hours and several measurements of intraocular pressure will be obtained to calculate an average pressure.
Participants will be randomly allocated to receive Combigan eye drops twice a day for 8 weeks or SLT, which will be performed in the optometrist's office or at a walk-in surgery center. Participants will continue to take their current glaucoma medication throughout this study. For participants assigned to the SLT group, the procedure will only take approximately 5

minutes. During the laser procedure, they will see some flashes of light and hear some clicks. One hour after the procedure, the investigators will check the pressure inside the eye and ask the participant to start taking one drop of prednisolone acetate 1% (a steroid eye drop) four times a day for the next 4 days to help reduce inflammation inside the eye and increase their comfort following the procedure.
Participants assigned to the Combigan group, will start using the drop twice a day in the study eye. Their doctor will not know which group they have been assigned to and will be not know whether they are taking Combigan eye drops or not or whether they received SLT.
Both groups of participants will also be asked to complete an eye drop diary documenting each date/time they administered an eye drop, which eye it went in, how many drops went into the eye and any issues they had with putting the eye drops into the eye (such as liquid fell out of the eye, too much liquid applied etc).
Eight weeks after starting the Combigan eye drops or having the SLT procedure performed, participants will have a follow-up examination to check intraocular pressure and look at structures inside the eye. The investigators will also check blood pressure, pulse, visual acuity, pupils, eye movement muscles,
intraocular pressure, and external ocular health.

What are the possible benefits and risks of participating?
The risks for SLT are minor and transient in nature, however participants might experience mild pain, discomfort, red eye, blurred vision, or light sensitivity. Rarely, SLT may cause increased inflammation inside the eye or a spike in intraocular pressure, which may require further treatment. The risks associated with prednisolone acetate 1% eye drops include an increase in intraocular pressure and cataract formation. The risks associated with Combigan eye drops include allergic conjunctivitis (irritation of the inner surface of the eyelid), conjunctival folliculosis (a type of conjunctivitis), conjunctival hyperemia (redness), eye pruritus (itching), ocular burning, and stinging. Participants may have a hypersensitivity reaction (allergy) to any of these medications.
To help minimize these potential side effects of the SLT and eye drop medication, the investigators will monitor participants closely and follow up with them 1 hour after the procedure. Additionally, a doctor will be on call 24 hours a day to deal with any possible complications that arise throughout the study.
Participants in this study may benefit as both treatments have been shown to lower intraocular pressure. However, there is no guarantee that there will be a
direct benefit to participants. Results from this study may benefit others in the future.

Where is the study run from?
Bennett and Bloom Eye Centers, Louisville, KY (USA)

When is the study starting and how long is it expected to run for?
May 2015 to July 2018

Who is funding the study?
The investigators are funding the study.

Who is the main contact?
Ian McWherter, ianmcwherter@upike.edu

Contact information

Type(s)

Scientific

Contact name
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1935 Bluegrass Ave, Suite 200
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Additional identifiers

Protocol serial number
0001

Study information

Scientific Title
A randomized, prospective, pilot study comparing the efficacy of Selective Laser Trabeculoplasty versus Brimonidine tartrate 0.2%/Timolol maleate 0.5% (Combigan, Allergan Inc.) in lowering intraocular pressure as adjunct therapy in Primary Open Angle Glaucoma.

Acronym
ODLASER STUDY

Study objectives
SLT and Combigan are both effective adjunct therapies for Primary Open Angle Glaucoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Pikeville Institutional Review Board, 21/06/2016, ref: MOD_15_0015

Study design
Single-center randomized investigator-masked prospective pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary Open Angle Glaucoma

Interventions
This study has two arms. Patients were randomized by selecting a prepackaged envelope with either the number 1 or 2 in it. Patients that select number 1 were assigned to group 1 and

received 360 degrees of SLT in one eye. Patients that select number 2 were assigned to group 2 and received brimonidine tartrate 0.2%/timolol maleate 0.5% (Combigan) bid in one eye. The patients were followed up 8 weeks after starting treatment.

Group 1: 360 degrees of the angle will be treated with 100 spots (+/-10 spots) evenly spaced apart. The pigment in the angle is graded and the initial power for grade 1 or 2 pigment is set as 1.0 mJ. The power is titrated in 0.1-mJ steps until there is a visible response of cavitation bubbles or pigment blanching. For grade 3 or 4 pigment the initial power is set at 0.8 mJ. The maximum energy is 2.0 mJ and the minimal energy is 0.4 mJ. Patients iwill be seen 1 hour following the procedure to ensure there is no IOP spike and started on prednisolone acetate 1% qid x 4 days in the study eye to improve patient comfort. No other postoperative drops will be permitted unless there is a pressure spike of 10 mmHg or greater from their baseline IOP at the 1 hour post-operative visit. If a pressure spike following the procedure occurs, one drop of rescue Alphagan (brimonidine tartrate) will be given. If this does not control the IOP spike then treatment to control the IOP will be at the doctor's discretion. All complications and adverse events will be recorded and closely monitored.

Group 2: Patients in the brimonidine tartrate 0.2%/timolol maleate 0.5% (Combigan) group will be started on the topical medication.

Subjects will be given a patient diary to monitor compliance with their medication. The diary will be a log that includes the date and time of each drop, the eye and number of drops administered, and any problems encountered. A contact number with questions about drop dosing will be given. Each group will be scheduled for a follow-up visit 8 weeks (+/- 2 weeks) after their respective therapy is initiated to assess the intraocular pressure reduction of the adjunct therapy. All patients will continue taking their current prostaglandin analog throughout the study.

If patients need treatment in both eyes the second eye will receive the same treatment as the first however only one eye will be eligible for the study. The eye with the higher baseline IOP will be included in the study, if the baseline IOP is equal in both eyes the right eye will be chosen as the study eye.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Intraocular pressure (IOP) at baseline and 8 weeks measured using Goldman tonometry. Baseline IOP was the average of two IOP measurements taken 30 minutes apart during the baseline exam. If the IOP measurements were greater than +/- 2 mmHg, a third IOP measurement was taken 30 minutes later. All follow up exams were within +/- 2 hour from the initial baseline exam to best control for diurnal fluctuations. Additionally, at each IOP measurement, two IOP readings will be taken and averaged.

Key secondary outcome(s))
1. Ocular abnormality or inflammation identified using slit lamp examination of the cornea, anterior chamber, and lens at baseline and 8 weeks after the procedure.
2. Visual acuity assessed using a standard Snellen chart at baseline and 8 weeks

Completion date
25/07/2018

Eligibility

Key inclusion criteria
1. Uncontrolled primary open angle glaucoma
2. Open angle on gonioscopy
3. Aged 25 to 90 years
4. Currently taking a prostaglandin analog, but IOP not controlled with monotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
23

Key exclusion criteria
1. Best corrected visual acuity worse than 20/40 in the study eye (meaning 20/50 or worse)
2. Hx of angle closure or an occludable angle on gonioscopy
3. Untreated IOP less than or equal to 21 mmHg
4. Patients who have used a second IOP lowering medication in the past 2 months
5. Angle recession on gonioscopy
6. Pseudoexfoliation glaucoma
7. Pigment dispersion glaucoma
8. Prior incisional glaucoma surgery
9. Prior Microinvasive Glaucoma Surgery (MIGS, istent, Endocyclophotocoagulation)
10. Previous SLT or Argon Laser Trabeculoplasty (ALT)
11. Previous Laser Peripheral Iridotomy (LPI)
12. Previous refractive surgery
13. Inflammatory eye disease
14. Contraindication to any of the topical medicines including asthma, chronic obstruction pulmonary disease, bradycardia, or a hypersensitivity reaction.
15. A change in dosage, or addition of, a systemic medication that could effect IOP during the study
16. Women who are pregnant or who intend to become pregnant in the next 4 months (as verbally asked during the medical history and consenting process, no formal pregnancy test will be administered for this study)
17. Patients with significant dementia who are not able to fully comprehend the informed consent

Date of first enrolment
22/06/2016

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Bennett and Bloom Eye Centers
1935 Bluegrass Parkway suite 200
Louisville
United States of America
40215

Sponsor information

Organisation
University of Pikeville Kentucky College of Optometry

ROR
https://ror.org/02fs2ee62

Funder(s)

Funder type
University/education

Funder Name
University of Pikeville Kentucky College of Optometry

Results and Publications

Individual participant data (IPD) sharing plan
The dataset is available on request from Ian McWherter at ianmcwherter@gmail.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/01/2021	28/09/2021	Yes	No
Participant information sheet	version V6.0	19/07/2017	14/12/2018	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		22/03/2019	28/09/2021	No	No
Protocol file	version V8.0	19/07/2017	14/12/2018	No	No