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New surgical procedure for implantation of glaucoma drainage tubes behind the iris

Submission date
19/04/2019

Recruitment status
No longer recruiting

Registration date
31/05/2019

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Glaucoma drainage devices (GDD) are frequently implanted in patients with glaucoma, most of the tube is implanted in the anterior chamber. However, this implantation causes problems in the cornea. To avoid this, many surgeons implant tubes in the posterior chamber (between the iris and the intraocular lens), although this is cumbersome and a more difficult surgical technique. In this study, a new method of inserting the tube was investigated for safety.

Who can participate?
Patients with glaucoma who require GDD tube implantation.

What does the study involve?
The study consists of teaching an easy, simple and effective method to implant GDD tubes in the posterior chamber. This surgical technique was designed and published by us about 10 years ago but is now modified.

What are the possible benefits and risks of participating?
The main benefits are to facilitate the surgical technique, shorten the time of the surgery and avoid intra and postoperative complications. The risks are scarce and not due to the surgical manoeuvre but to the evolution of glaucoma.

Where is the study run from?
Clínica Universidad de Navarra, Pamplona, Spain.

When is the study starting and how long is it expected to run for?
January 2009 to January 2019.

Who is funding the study?
Universidad de Navarra, Spain.

Who is the main contact?
Prof. Javier Moreno-Montañés,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2019-001852-20

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
65

Study information

Scientific Title
Surgical technique for ab interno implantation of glaucoma drainage devices (GDD) in the posterior chamber in patients with glaucoma

Acronym
NSTAIIGDDTPC

Study objectives
The hypothesis of our study is that it is easier and more comfortable for a surgeon to insert a tube behind the iris (therefore without direct vision) by traction of the tube from inside the eye through a prolene suture compared to the usual method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Study approved by the ethical committee of the University of Navarra (Edificio Central, Campus universitario, 31009 Pamplona, Navarra, Spain; +34 948296500; ceic@unav.es), ref: 2019.062

Study design
Retrospective study

Primary study design
Observational

Secondary study design
Surgical study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Glaucoma

Interventions
Implantation of the glaucoma drainage tube into the posterior chamber using a 10/0 prolene needle. The new technique begins with the passage of one of two straight needles existing at each end of a 10-0 Polypropylene suture through the GDD tube. A 23-gauge needle then is inserted at an angle 180° away and passed from the anterior to the posterior chamber and finally through the sclera. The two suture straight needles from the 10-0 Polypropylene suture are positioned in the lumen of the 23-gauge needle. The 23-gauge needle is then extracted from the eye by passing the 2 needles through the lumen. The suture remains inside the posterior chamber, and the tube is inserted into the posterior chamber by pulling on the suture from the other side.

The participants included in this study were patients who had to be operated on for glaucoma surgery using a Glaucoma Drainage Device (GDD). They were therefore patients with glaucoma with a surgical indication. These patients signed informed consent. The duration of the follow-up was as long as possible until the study was prepared for publication.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Adequate and correct placement of the tube and ease of surgical technique assessed by the surgeon who performed the operation one day after the procedure.

Secondary outcome measures
1. Intraocular pressure control after the follow-up period measured at all postoperative visits with a Goldmann tonometer.
2. Presence of complications following surgery.

Overall study start date
01/01/2009

Completion date
01/01/2019

Eligibility

Key inclusion criteria
Patients with advanced glaucoma who have undergone drainage device implantation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1.Cataract surgery

Date of first enrolment
01/02/2009

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
Spain

Study participating centre
Clínica Universidad de Navarra
Avenida Pío XII, 36

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Sponsor information

Organisation
Clínica Universidad de Navarra

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Sponsor type
Hospital/treatment centre

Website
https://www.cun.es/

ROR
https://ror.org/03phm3r45

Funder(s)

Funder type
University/education

Funder Name
Universidad de Navarra

Alternative Name(s)
University of Navarra

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

Spain

Results and Publications

Publication and dissemination plan
Publication in BMC Ophthalmology as a Technical Advance

Intention to publish date
05/05/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/02/2020	26/10/2020	Yes	No