

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

Submission date 19/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2020	Condition category Eye Diseases	<input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2019-001852-20

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

01/01/2019

Eligibility

Key inclusion criteria

Patients with advanced glaucoma who have undergone drainage device implantation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Pamplona

Spain

31008

Sponsor information**Organisation**

Clínica Universidad de Navarra

ROR

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

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