Assessing different pre-operative protocols for cataract surgery in patients taking tamsulosin

Submission date 18/09/2012	Recruitment status No longer recruiting	Prospectively registeredProtocol
Registration date 19/10/2012	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 19/10/2017	Condition category Eye Diseases	Individual participant data

Plain English summary of protocol

Background and study aims

Intraoperative floppy iris syndrome (IFIS) is a complication that can occur during cataract extraction. It has linked with the use of the medication tamsulosin. IFIS may cause the pupil to constrict and increase the risk of vision-threatening complications of cataract surgery, particularly when surgeons are unaware of the patient's medical history. Previous studies found that the use of a wick pre-soaked in standard pupil-dilating (mydriatic) and non-steroidal anti-inflammatory drugs was as effective as or better than the conventional repeated use of drops before cataract surgery. The aim of this study is to assess the effectiveness of a mydriatic cocktail-soaked sponge as an alternative method of pupil dilation in high-risk patients taking tamsulosin.

Who can participate?

Male patients (either taking tamsulosin or not) undergoing cataract surgery

What does the study involve?

Patients taking tamsulosin are randomly allocated into two groups. One group have their pupils dilated using a mydriatic cocktail-soaked sponge. The other group have their pupils dilated with conventional repeated eye drops. Patients not taking tamsulosin have their pupils dilated using the mydriatic cocktail-soaked sponge. Any side effects associated with the use of the sponge are recorded. All patients undergo standard cataract surgery. Pupil size, surgical complications, use of iris hooks, operation time and iris thickness are measured.

What are the possible benefits and risks of participating? Participants benefit from an extended assessment before their operation, which may further reduce surgical complications. The risks are not higher than standard cataract surgery.

Where is the study run from? Thy-Mors Hospital (Denmark)

When is the study starting and how long is it expected to run for? October 2012 to February 2013 Who is funding the study? Thy-Mors Hospital (Denmark)

Who is the main contact? Dr Janos Hargitai

Contact information

Type(s) Scientific

Contact name Dr Janos Hargitai

Contact details Thy-Mors Hospital Department of Ophthalmology Højtoftevej 2 Thisted Denmark 7700

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Efficacy of mydriatic cocktail-soaked sponge pupil dilation in patients using tamsulosin

Study objectives

A mydriatic-cocktail soaked cellulose sponge showed satisfactory effect in dilating pupils preoperatively, however this method was not tested in high risk patients such as patients taking tamsulosin.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design

Prospective randomised controlled study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Cataract

Interventions

Phacoemulsification cataract surgery

The tamsulosin group will be randomized into two groups: Group 1 will be dilated using a mydriatic cocktail-soaked sponge Group 2 will be dilated with conventional repeated eyedrop regimen

The control group (Group 3) will be dilated using the mydriatic cocktail- soaked sponge

Intervention Type

Mixed

Primary outcome measure

Pupillary diameter

Secondary outcome measures

- 1. Adverse effects related to the wick use
- 2. Intraoperative complications
- 3. Use of iris hooks
- 4. Duration of operation
- 5. Preoperative iris thickness

Overall study start date 01/10/2012

Completion date 01/02/2013

Eligibility

Key inclusion criteria

Tamsulosin medication
 Cataract

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants 50

Key exclusion criteria 1. Previous ocular surgery 2. Posterior synechiae 3. The use of drops other than artificial tears

Date of first enrolment 01/10/2012

Date of final enrolment 01/02/2013

Locations

Countries of recruitment Denmark

Study participating centre Thy-Mors Hospital Thisted Denmark 7700

Sponsor information

Organisation Thy-Mors Hospital (Denmark)

Sponsor details

Department of Ophthalmology Højtoftevej 2 Thisted Denmark 7700

Sponsor type Hospital/treatment centre

Funder(s)

Funder type Hospital/treatment centre

Funder Name Thy-Mors Hospital (Denmark)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	20/12/2013		Yes	No