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

Submission date
18/09/2012

Recruitment status
No longer recruiting

Registration date
19/10/2012

Overall study status
Completed

Last Edited
19/10/2017

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

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

Primary study design
Interventional

Study design
Prospective randomised controlled study

Study type(s)
Treatment

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(s)
Pupillary diameter

Key secondary outcome(s)
1. Adverse effects related to the wick use
2. Intraoperative complications
3. Use of iris hooks
4. Duration of operation
5. Preoperative iris thickness

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Tamsulosin medication
2. Cataract

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Thy-Mors Hospital (Denmark)

Results and Publications

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?
Results article	results	20/12/2013		Yes	No