

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

Submission date 18/09/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/10/2017	Condition category Eye Diseases	<input type="checkbox"/> 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

Protocol serial number
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

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