

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

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

**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**

1. Tamsulosin medication
2. 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?
<a href="#">Results article</a>	results	20/12/2013		Yes	No