

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial to compare the efficacy Tamsulosin and placebo in prevention of urinary retention after general anesthesia in cataract surgery

Protocol summary

Summary

Objectives: To determine the prevalence of urinary retention in post general anesthesia in cataract surgery and the effect of Tamsulosin in preventing this complication
Design and interventions: This clinical trial was carried out on 67 patients who had inclusion criteria of the study. They were divided randomly in two groups; the first group was consisted 32 patients received Tamsulosin and the other 35 subjects received placebo as control group. Inclusion criteria: patients with spontaneous urine output less than 100 ml in the first eight hours after surgery, patients with abdominal discomfort and completely distended palpable bladder
Exclusion criteria: Congestive Heart Failure, Myocardial Infarction, Renal Failure, Hypotension (Systolic Blood Pressure less than 100 mmHg), hypersensitivity to the drug, IPSS score greater than 25 or less than 15 and patients with a permanently Foley catheter
Outcome variables: prevention of urinary retention after surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111411469N1**

Registration date: **2013-02-11, 1391/11/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-11, 1391/11/23

Registrant information

Name

Arezou Karampourian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0572

Email address

a.karampourian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2010-07-21, 1389/04/30

Expected recruitment end date

2010-12-21, 1389/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare the efficacy Tamsulosin and placebo in prevention of urinary retention after general anesthesia in cataract surgery

Public title

Tamsulosin and preventing of postoperative urinary retention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : No contraindications for general anesthesia and general Surgery. Patients with spontaneous urine output less than 100 ml in the first eight hours after surgery, and completely distended

palpable bladder Exclusion criteria: Congestive Heart Failure, Myocardial Infarction, Renal Failure, Hypotension (Systolic Blood Pressure less than 100 mmHg), hypersensitivity to the drug, IPSS score greater than 25 or less than 15 and patients with a permanently Foley catheter

Age

From **52 years** old to **84 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization was based on blocked simple randomization (each group was 6 patients). The study was single blind study, because physician awareness doesn't play any roll in patient's urinary retention but patient's awareness can affect the retention and patient can try to void and obscured the retention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Shaheed Fahmideh St. Hamadan University of Medical Sciences

City

Hamadan

Postal code

6517838698

Approval date

2007-05-05, 1386/02/15

Ethics committee reference number

15162/9/35/16/P

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H40.1

ICD-10 code description

Capsular glaucoma with pseudo exfoliation of lens (H40.1

Primary outcomes

1

Description

Urinary Retention

Timepoint

Every one hour, until 8 hours from surgery, patients will be examined for urination or probable urinary retention.

Method of measurement

Failure to void and patients need to urethra catheterization

Secondary outcomes

1

Description

Floppy Iris

Timepoint

During surgery

Method of measurement

Any iris dropping during surgery that report by surgeon and interfere with surgery

Intervention groups

1

Description

Intervention 1: Tablet Tamsulosin Hydrochloride 0.4 mg, once a day for four days, Brand name Flomax , manufacturer Farabi Pharmaceutical

Category

Prevention

2

Description

Intervention 2: Placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Samavat Morteza

Street address

Farshchian Hospital, Mirzadeh Eshghi St., Hamadan
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor for research, Hamadan University of
Medical Sciences

Full name of responsible person

Tavilani Haydar

Street address

Shaheed Fahmideh St. Hamadan University of Medical
Sciences

City

Hamadan

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Chancellor for research, Hamadan University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Karampourian Arezo

Position

MSN/ Faculty member of Hamadan University of
Medical Sciences

Other areas of specialty/work

Street address

Shaheed Fahmideh St. Hamadan University of Medical
Sciences

City

Hamadan

Postal code

6517838698

Phone

+98 81 1838 0572

Fax

Email

a.karampourian@umsha.ac ; karampor1@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urology and Nephrology Research Center, Hamadan
University of Medical Sciences

Full name of responsible person

Mousavi Bahar Seyed Habibollah

Position

Endourologic Surgeon

Other areas of specialty/work

Street address

Shaheed Fahmideh St. Hamadan University of Medical
Sciences

City

Hamadan

Postal code

6517838698

Phone

+98 83 80572

Fax

Email

shmbahar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shaheed Fahmideh St. Hamadan University of Medical
Sciences

Full name of responsible person

Karampourian Arezo

Position

MSN/Faculty member of Hamadan University of
Medical Sciences

Other areas of specialty/work

Street address

Shaheed Fahmideh St. Hamadan University of Medical
Sciences

City

Hamadan

Postal code

6517838698

Phone

+98 81 1838 0572

Fax

Email

a.karampourian@umsha.ac.ir ;
karampor1@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty