Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficacy of combination therapy with "Tamsulosin and Meloxicam” for the management of Lower Urinary Tract Symptoms suggestive of Benign Prostatic HyperplasiaL: a randomized double-blind placebo–control clinical trial

Protocol summary

Summary

Inflammation and inflammatory mediators have an important role in the pathophysiology of benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS). We will assess the efficacy of administration of combination therapy with “Tamsulosin and Meloxicam” with “Tamsulosin and placebo” in the management of LUTS suggestive of BPH. In our study which is a randomized double- blind placebo –control clinical trial, 44 men aged 50 to 80 years with LUTS suggestive of BPH will be enrolled. They randomly will be allocated in two groups. One group receives Tamsulosin 0.4mg/daily and Meloxicam 15mg/daily and another group receives Tamsulosin 0.4mg/daily and Placebo once daily. We assess the difference of International Prostate Symptom Score (IPSS), maximum of urinary flow rate (Qmax) and Post Void Residue (PVR) before treatment and 3 months after that.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009304582N4**
Registration date: **2010-11-13, 1389/08/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-13, 1389/08/22

Registrant information

Name

Ali Hamidi Madani

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1552 5259

Email address

hamidimadani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center of Guilan University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2010-10-22, 1389/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of combination therapy with "Tamsulosin and Meloxicam” for the management of Lower Urinary Tract Symptoms suggestive of Benign Prostatic HyperplasiaL: a randomized double-blind placebo–control clinical trial

Public title

The assessment of the efficacy of combination therapy with "Tamsulosin and Meloxicam” for the management of Lower Urinary Tract Symptoms suggestive of Benign Prostatic Hyperplasia

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: - age between 50 to 80 years old - Patients with LUTS - International Prostate Symptom Score (IPSS)≥ 12 - 5ml/s < maximum of urinary flow rate (Qmax) < 15 ml/s - volume of prostate less than 50ml. Exclusion criteria: - prostate cancer - history of previous surgery of prostate - liver disease - bleeding diathesis - history of Gastrointestinal Bleeding (GIB) or Peptic Ulcer Disease (PUD) - Prostate Specific Antigen (PSA) > 10mg/ml - Post Void Residue (PVR)≥ 200ml - side effects of Meloxicam consumption - acute urinary retention during treatment - side effects of Tamsulosin consumption.
Age
From **50 years** old to **80 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Research Assisstant of Guilan University of Medical Sciences
Street address
The Research Assisstant of Guilan University of Medical Sciences
City
Rasht
Postal code
Approval date
2010-05-22, 1389/03/01
Ethics committee reference number
1023

Health conditions studied

1

Description of health condition studied
Lower Urinary Tract Symptoms
ICD-10 code
N21
ICD-10 code description
Calculus of lower urinary tract

2

Description of health condition studied
Benign Prostatic Hyperplasia
ICD-10 code
N40
ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
variations of International Prostate Symptom Scor (IPSS)
Timepoint
3 months
Method of measurement
IPSS questaionnaire

2

Description
variations of Qmax
Timepoint
3 months
Method of measurement
uroflometery

3

Description
variations of Post Voided Residue (PVR)
Timepoint
3 months
Method of measurement
Sonography

Secondary outcomes

1

Description
Side effects of meloxicam
Timepoint
3 months
Method of measurement
questionnaire

Intervention groups

1

Description
0.4mg tamsulosin daily and placebo daily for 3 months
Category
Placebo

2

Description
0.4mg tamsulosin daily and 15mg meloxicam daily for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urology Clinic of Razi Hospital
Full name of responsible person
Dr. Alireza Farzan
Street address
Razi Hospital
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Center
Full name of responsible person
Dr. Siavash Falahatkar, Manager of Urology Research Center
Street address
Urology Research Center, Razi Hospital
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Center
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
Urology Research Center
Full name of responsible person
Dr. Alireza Farzan
Position
Coworker/Resident of Urology
Other areas of specialty/work
Street address
Urology Research Center, Razi Hospital
City
Rasht
Postal code
4144895655
Phone
+98 13 1552 5259
Fax
+98 13 1552 5259
Email
farzan_alireza@yahoo.com; urc1384@yahoo.com
Web page address
www.urc.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urology Research Center
Full name of responsible person
Dr. Ali Hamidi Madani
Position
Assisstant Prof.
Other areas of specialty/work
Street address
Urology Research Center, Razi Hospital
City
Rasht
Postal code
4144895655
Phone
+98 13 1552 5259
Fax
+98 13 1552 5259
Email
a42hamidi2000@yahoo.com; urc1384@yahoo.com
Web page address
www.urc.ir

Person responsible for updating data

Contact
Name of organization / entity
Urology Research Center
Full name of responsible person
Samaneh Esmaeili
Position
Urology Research Center secreter/ Bachlor

Other areas of specialty/work

Street address

Urology Research Cente, Razi Hospital

City

Rasht

Postal code

4144895655

Phone

+98 13 1552 5259

Fax

+98 13 1552 5259

Email

samaneh_815@yahoo.com; urc1384@yahoo.com

Web page address

www.urc.ir

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