Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Sustained-Released Diclofenac with Placebo on Urethral Dilatation Pain score in two groups called Intervention and Control group, in Urethral Stricture Patients

Protocol summary

Study aim
Effects of Sustained-Released Diclofenac on Urethral Dilatation Pain

Design
Clinical trial with Control group, Parallel groups, single blind, Phase 3, 40 Patients, table of random numbers used for allocation

Settings and conduct
The present study is a single blind randomized clinical trial that was performed on 40 patients referred to the urology clinic of Ghaem Hospital due to urethral stricture from March of 2020 to the end of 2021. Eligible patients were randomly divided into two groups after obtaining informed consent. The intervention group received 100 mg sustained-released Diclofenac tablet 10 hours before urethral dilatation. Patients in the control group received Placebo. Demographic information (age, occupation, etc.), pain during the procedure and 1 hour after the procedure (VAS), the need to take analgesic and side effects were collected in a checklist

Participants/Inclusion and exclusion criteria
Men older than 20 years old, Single stricture and less than 1.5 cm in length urethral stricture due to Balanitis Xerotica Obliterans history of hepatic, renal or gastric diseases patience refusal of participation History of NSAID Hypersensitivity Dangerous Diclofenac Side Effects

Intervention groups
Case group received 100 mg of Diclofenac tablet 10 hours before urethral dilatation while Control group received Placebo

Main outcome variables
Pain score during urethral dilatation based on visual analogue scale(VAS), Pain score 1 hour after urethral dilatation based on VAS, the need to take analgesic during the first 24 hours after the procedure, Side effects during the first 24 hours after the procedure.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220711055433N1**
Registration date: **2022-07-19, 1401/04/28**
Registration timing: **retrospective**

Last update: **2022-07-19, 1401/04/28**
Update count: **0**

Registration date
2022-07-19, 1401/04/28

Registrant information
Name
Amir Abbas Asadpour
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3843 2256
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-23, 1399/03/03
Expected recruitment end date
2020-11-21, 1399/09/01
Actual recruitment start date
2020-05-23, 1399/03/03
Actual recruitment end date
2021-06-22, 1400/04/01
Trial completion date
2021-09-22, 1400/06/31

Scientific title
Comparison of Sustained-Released Diclofenac with Placebo on Urethral Dilatation Pain score in two groups called Intervention and Control group, in Urethral Stricture Patients

Public title
Effects of Diclofenac on Urethral stricture treatment pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male gender Older than 20 years old Single urethral stricture and stricture length less than 1.5 cm

Exclusion criteria:
Urethral stricture due to Balanitis Xerotica Obliterans History of hepatic, renal or gastric diseases Patient refusal of participation History of NSAID Hypersensitivity

Age
From **20 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients qualified for this clinical trial, were given numbers 01 to 40 considering time of entering the trial. 20 of these numbered patients were allocated to Intervention group using Simple Randomization Method by Fisher and Yates Random Number Table and the other 20 patients were allocated to Control group. So at the time of qualification, the researcher was not aware what each patient's group would be.

Blinding (investigator's opinion)
Single blinded

Blinding description
Each Participant received one envelope containing one Diclofenac tablet or one Placebo tablet similar in color, size, taste and odor to Diclofenac. The envelopes were labeled two different numbers so that researchers knew the content of each envelope and the group each participant was in but the participants themselves were not aware whether they've received Diclofenac or Placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Ghoreshi Department, Daneshgah St

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2020-01-28, 1398/11/08

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.878

Health conditions studied

1

Description of health condition studied
Urethral Stricture

ICD-10 code
N35

ICD-10 code description
Urethral stricture

Primary outcomes

1

Description
Pain during urethral dilatation

Timepoint
Immediately after urethral dilatation

Method of measurement
Based on Visual Analogue Scale

2

Description
Pain 1 hour after urethral dilatation

Timepoint
1 hour after urethral dilatation

Method of measurement
Based on Visual Analogue Scale

Secondary outcomes

1

Description
The need to take analgesics

Timepoint
24 hours after urethral dilatation

Method of measurement

Yes or No

2

Description
Side effects due to Diclofenac
Timepoint
24 hours after urethral dilatation
Method of measurement
Yes or No

Intervention groups

1

Description
Intervention group: one sustained-release Diclofenac tablet (100mg) Sobhan Darou taken orally 10 hours before urethral dilatation
Category
Treatment - Drugs

2

Description
Control group: one tablet of Placebo similar to Diclofenac tablet in size, taste and color taken orally 10 hours before urethral dilatation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Amir Abbas Asadpour
Street address
Ghaem Hospital, Ahmadabad Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayor Mobarhan
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amir Abbas Asadpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology
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Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available