

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

efficacy of meatal dilatation with topical hydrocortisone ointment in the treatment of meatal stricture

Protocol summary

Study aim

efficacy of dilatation with topical corticosteroid ointment in patients with meatal stricture

Design

Clinical trial without a control group; phase2; in 50 members group

Settings and conduct

This study will be done on boys under 15 years old with meatal stricture who refer to a urology clinic in Sabzevar. After taking history and configuring the meatal stricture; dilatation with nelaton catheter will be done to 10 french. Then weekly for one month will be continued. Hydrocortisone acetate 1% will be prescribed for BID use in the home. One month after the last dilatation; patients will be re_ evaluate for improvement of the meatal stricture with taking history and meatus calibration.

Participants/Inclusion and exclusion criteria

All boys under 15 years old with meatal stricture will be in the study. If there is a history of meatus surgery except for circumcision; urogenital anomalies; history or recurrent UTI; renal failure secondary to meatal stricture; urinary reflux secondary to meatal stricture and age more than 15 years old they will be out of the study.

Intervention groups

In this study, we will examine the efficacy of dilatation with hydrocortisone ointment as a non_ invasive treatment while the standard treatment in patients with meatal stricture is meatotomy surgery. dilatation will be done with the nelaton catheter to 10 french then weekly till one month this will be continued. hydrocortisone acetate 1% will be prescribed for BID use at home.

Main outcome variables

Resolving the meatal stricture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210729052011N1**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Neda Zahraei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4723 3980

Email address

nedazahraei9593@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy of meatal dilatation with topical hydrocortisone ointment in the treatment of meatal stricture

Public title

efficacy of topical hydrocortisone ointment in meatal

stricture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All boys under 15 years old with meatal stricture
Exclusion criteria:
History of meatus surgery except circumcision Urogenital system anomalies Renal failure secondary to meatal stricture Urinary reflux secondary to meatal stricture Recurrent UTI

Age
From **1 month** old to **15 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Shohada hastei Blvd; Sabzevar Town; Sabzevar University of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2020-02-03, 1398/11/14

Ethics committee reference number

IR.MEDSAB.REC.1398.094

Health conditions studied

1

Description of health condition studied

Meatal stricture

ICD-10 code

N35.010

ICD-10 code description

Post-traumatic urethral stricture, male, meatal

2

Description of health condition studied

Meatal stricture

ICD-10 code

N35.111

ICD-10 code description

Postinfective urethral stricture, not elsewhere classified, male, meatal

3

Description of health condition studied

Meatal stricture

ICD-10 code

N99.110

ICD-10 code description

Postprocedural urethral stricture, male, meatal

Primary outcomes

1

Description

the amount of meatal stricture with clinical examination and qualitative report of it

Timepoint

measuring meatal stenosis at the beginning of the study and then 2 month after intervention

Method of measurement

measuring will be done with nelaton catheter and will be reported in a qualitative way.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after taking history and configuring meatal stricture, dilatation will be done with nelaton catheter and hydrocortisone acetate 1% which manufactured in Emad Darman Pars company to 10 French. then weekly till one-month dilatation will be continued in the same way. topical hydrocortisone acetate 1% ointment will be prescribed for use at home twice a day. one month after the last meatus dilatation, the patient's meatal stricture improvement will be examined by taking history and meatus calibration.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasee Hospital in Sabzevar

Full name of responsible person

Doctor Hamidreza Baghani Aval

Street address

Shohada Hastei Blv; Vasee Hospital

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613988467

Phone

+98 51 4465 1300

Email

hamidreza_baghani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr Mohammadhosein Saghi

Street address

Sabzevar University of Medical science; Shohada
Hastei Blv; Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617213112

Phone

+98 51 4401 8300

Email

saghi9@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Doctor Hamidreza Baghani Aval

Position

Associate professor of Urology

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Sabzevar Medical University of Science; Shohada
Hastei Blv; Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

961383136

Phone

+98 51 4401 1300

Email

hamidreza_baghani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Doctor Hamidreza Baghani Aval

Position

Associate professor of Urology

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Sabzevar Medical University of Science; Shohada
Hastei Blv; Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

961383136

Phone

+98 51 4401 1300

Email

hamidreza_baghani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Neda Zahraei

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No 6, Besat5 Ave, Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9618645151

Phone

+98 51 4723 3980

Fax**Email**

nedazahraei9593@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available