Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intra-rectal midazolam administration before urodynamic study on pain, stress and cooperation of patient during test in women

Protocol summary

Study aim
Determining the effect of intra-rectal administration of midazolam before urodynamic testing on pain, stress and patient cooperation during testing in women

Design
Clinical trial with control group, with parallel, non-blind, randomized, phase 3 groups on 80 patients. Random allocation software was used for randomization.

Settings and conduct
The study will be performed on women referred to the urodynamics Department of Khorshid Hospital in 1400. Patients who meet the inclusion criteria are randomly divided into two groups. In one group, urodynamic test is performed ten minutes after midazolam intrarectal administration and in the control group without midazolam. The patient's pain and stress are assessed using rulers. Patients' cooperation during the test will be recorded by the technician after the completion of the test. Parameters of blood pressure, heart rate and arterial blood oxygen saturation percentage are monitored and recorded before and during the test.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Women between the ages of 20 to 75, 2- Having urinary disorders, 3- Candidates for urodynamic testing Exclusion criteria : 1- History of heart and respiratory diseases, 2- History of known psychiatric disorders, 3-History of taking sedatives or anti-anxiety drugs 1 month before the test, 4- History of spinal cord injury and 5- History of bladder sensation disorder.

Intervention groups
In the case group (intervention), 10 minutes before the start of the test, 0.3 mg depending on the patient's weight and with a maximum dose of 15 mg midazolam is administered rectally and then the urodynamic test is done in a standard way. In the control group, urodynamic testing will be performed without the prescription of midazolam and in a standard way.

Main outcome variables
Reduce patient pain and stress; Increase patient cooperation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210122050105N1**
Registration date: **2021-01-25, 1399/11/06**
Registration timing: **prospective**

Last update: **2021-01-25, 1399/11/06**
Update count: **0**

Registration date
2021-01-25, 1399/11/06

Registrant information

Name
Narjes Saberi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3668 9239

Email address
narjessaberi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-03, 1399/11/15

Expected recruitment end date
2022-02-04, 1400/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of intra-rectal midazolam administration before urodynamic study on pain, stress and cooperation of patient during test in women

Public title
Effect of intra-rectal midazolam administration before urodynamic study on pain, stress and cooperation of patient during test in women

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Women between the ages of 20 to 75 Having urinary disorders Candidates for urodynamic testing
Exclusion criteria:
History of heart and respiratory diseases History of known psychiatric disorders History of taking sedatives or anti-anxiety drugs 1 month before the test History of spinal cord injury History of sensory bladder disorder

Age
From **20 years** old to **75 years** old

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with inclusion criteria were randomly divided into two groups using random allocation software. It is an individual randomization unit. Randomization is done in a simple way. A list of random numbers created with computer statistical software is used. It is not possible to blind the technician, but Collectors of data related to the patient's pain and stress as well as data analysts are blind to the intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Ostandari Street, Khorshid Hospital, Urology Department
City
Isfahan
Province
Isfehan
Postal code
8169653979

Approval date
2021-01-03, 1399/10/14

Ethics committee reference number
IR.MUI.MED.REC.1399.881

Health conditions studied

1

Description of health condition studied
Evaluation of the sedative effect of midazolam in reducing pain and stress and increasing patient cooperation during urodynamic testing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Evaluation of the effect of rectal administration of midazolam on the patient's pain during urodynamic test

Timepoint
after the test

Method of measurement
Pain measuring ruler that measures the patient's pain from 0 to 10 at the same time as the number and shape.(Visual Analogue Scale)

2

Description
Evaluation of the effect of rectal administration of midazolam on patient stress during urodynamic testing

Timepoint
after the test

Method of measurement
stress measuring ruler that measures the patient's stress from 0 to 5 at the same time as the number and shape.(Visual Analogue Scale)

3

Description
Evaluation of the effect of rectal administration of midazolam on patient cooperation during urodynamic testing

Timepoint
after the test

Method of measurement

This index is graded from 0 to 3 and will be recorded by the technician performing the test after completing the steps. The degree of cooperation is classified as follows: 0, indicates poor cooperation (non-cooperation, the patient disrupts the test and needs to repeat the test); 1, indicates sufficient cooperation (patient cooperation is not complete but there is no need to repeat the test); 2, indicates good cooperation (cooperation is appropriate for most of the test and the patient cooperates for a better test); 3, Excellent cooperation (cooperates fully with the technician and executes instructions at all times during the test).

4

Description
Evaluation of changes in the patient's blood pressure after rectal administration of midazolam before performing urodynamic test
Timepoint
At the beginning of the study (before the intervention). During the test (after the intervention)
Method of measurement
Mercury sphygmomanometer

5

Description
Evaluation of changes in patient heart rate after rectal administration of midazolam before urodynamic test
Timepoint
At the beginning of the study (before the intervention). During the test (after the intervention)
Method of measurement
Pulse oximeter device

6

Description
Investigation of changes in saturation percentage of arterial blood oxygen saturation of the patient after rectal administration of midazolam before performing urodynamic test
Timepoint
At the beginning of the study (before the intervention). During the test (after the intervention)
Method of measurement
Pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the case group (intervention), 10 minutes before the start of the test, 0.3 mg according to the patient's weight and with a maximum dose of 15 mg midazolam is administered rectally via a catheter.15 ml midazolam ampoule is used for this purpose. To do this, insert the catheter about 10 cm into the anus and after administering midazolam, remove the tube extension. Urodynamic testing is then performed on patients in a standard manner. Before the intervention and after the intervention, during the test, the patients' blood pressure, heart rate and arterial blood oxygen saturation percentage, and at the end of the test, the amount of pain and stress and the patient's cooperation are evaluated and recorded.
Category
Treatment - Drugs

2

Description
Control group: In the control group, urodynamic test is performed by the standard method without rectal administration of midazolam, before and during the test, patients' blood pressure, heart rate, and arterial blood oxygen saturation percentage and at the end of the test, the amount of pain and stress and patient cooperation are evaluated and recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Khorshid Hospital
Full name of responsible person
Narjes Saberi
Street address
Isfahan, Ostandari Ave, Khorshid Hospital, Urology Ward
City
Isfahan
Province
Isfehan
Postal code
8169653979
Phone
+98 31 3222 2127
Email
narjessaberi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Narjes Saberi
Street address
Isfahan University of Medical Sciences,Isfahan,Iran
City
Isfahan
Province

Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
narjessaberi@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Narjes Saberi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Isfahan University of Medical Sciences,Isfahan,Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3222 2127
Email
narjessaberi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Narjes Saberi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Isfahan University of Medical Sciences,Isfahan,Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
narjessaberi@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Narjes Saberi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Ostandari Ave, Almahdi hospital, Urology ward
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 9239
Fax
Email
narjessaberi@med.mui.ac.ir

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