

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparison the Effect of Coughing Technique (CT) and Nose Taking Technique (NTT) on Pain Intensity During Urinary Catheterization

Protocol summary

Study aim

Determining the effect of using deep cough technique, and the technique of pressing the tip of the nose on pain intensity of urinary catheterization

Design

The present study is a randomized clinical trial with a control group without blinding that will be performed on 75 patients requiring urinary catheterization.

Settings and conduct

Sampling will be done in Imam Khomeini Educational, Research and Treatment Center. After obtaining the code of ethics from the university, we refer to the sampling place. Patients who need urinary catheterization, both diagnostically and therapeutically, according to the relevant specialist, will be selected as a sample if they meet the inclusion criteria. First, informed consent will be obtained from them and then their demographic information will be recorded. After entering the study, patients will be randomly divided into three groups: first intervention, second intervention and control group.

Participants/Inclusion and exclusion criteria

People 18-65 years old who need urinary catheterization

Intervention groups

The first intervention group: In the first group, patients are taught to do a deep cough before the catheter is inserted. Pause for 10 seconds and then do a second cough. The nurse inserts a urinary catheter into the urethra while the patient is coughing for a second time. Second intervention group: In the second intervention group, patients are instructed to squeeze the tip of the nose and exhale and squeeze at the same time with the glottis closed. The nurse inserts the urinary catheter into the urethra at the same time.

Main outcome variables

Pain of catheterization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191217045764N3**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Ali Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

abedia1371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Coughing Technique (CT) and Nose Taking Technique (NTT) on Pain Intensity During Urinary Catheterization

Public title

Comparison the Effect of Coughing Technique (CT) and Nose Taking Technique (NTT) on Pain Intensity During Urinary Catheterization

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Be a man People 18-65 years old who need catheterization No problem in feeling and understanding pain like nephropathies The patient has the ability to cooperate in assessing pain (no mental disorders)

Exclusion criteria:

Catheterization should not be performed within the range of effects of narcotic and non-narcotic analgesics. Hematuria The patient has a history of heart disease People with active urinary tract infections Score above 39 mm Hg based on the VAS scale Pre-existing urinary catheter Urinary tract stenosis Pre-existing urinary tract pain (for example: Patients with chronic pelvic pain syndromes, interstitial cystitis) Neurological patients with decreased level of consciousness anesthetized and intubated Patients

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Permutation blocks were used for random allocation. Eligible patients were divided into three groups of first, second and control groups (Each group is 25 people). Our 6-state blocks and how the different permutations should be, using random numbers on the back of Dr. Kazem Mohammad's book of statistics and with their eyes closed, first a number was determined and the different permutations of the 6-state blocks were recorded in sequence from left to right. So that if the number one came A, and the number 2 belonged to group B and the number 3 belonged to group C. And different modes of ABCABC, AABBC, were identified for the Case and control groups.

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 Esfarayen University of Medical Sciences

Street address

No. 70, Imam Reza Alley12 , Imam Reza Ave

City

Esfarayen

Province

North Khorasan

Postal code

۷۶۹۸۱-۹۶۶۱۸

Approval date

2020-08-19, 1399/05/29

Ethics committee reference number

IR.ESFARAYENUMS.REC.1399.012

Health conditions studied

1

Description of health condition studied

The pain of urethral catheterization

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measuring the pain of urinary catheterization

Timepoint

Before, immediately and 15 minutes after urinary catheterization

Method of measurement

Visual analog scale, Numeric pain rating scale, Wong-Baker pain Rating scale

Secondary outcomes

1

Description

Blood Pressure (BP)

Timepoint

Before, immediately after, and 15 minutes after the intervention

Method of measurement

Use of BC1000 Barometer cuff

2

Description

Pulse Rate (PR)

Timepoint

Before, immediately after, and 15 minutes after the

intervention

Method of measurement

Check the pulse rate with the using of radial artery

3

Description

Respiration Rate (RR)

Timepoint

Before, immediately after, and 15 minutes after the intervention

Method of measurement

Check the patient's number of respiratory rate per minute

Intervention groups

1

Description

Intervention group: In the first group, patients are taught to first do a deep cough, pause for 10 seconds, and then do a second cough. The nurse inserts a urinary catheter into the urethra during the second cough.

Category

Other

2

Description

Intervention group: Patients in the second group are instructed to squeeze the tip of the nose and exhale compressively at the same time as the closed glottis, so that the nurse inserts the urinary catheter into the urethra to the end.

Category

Other

3

Description

Control group: In the control group, urinary tract catheterization is performed routinely.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Imam Khomeini Hospital

Full name of responsible person

Javad sedaghati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfarayen 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

Esfarayen University of Medical Sciences

Full name of responsible person

Ali Abedi

Position

Faculty member, instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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

"No more 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