

# 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)

##### Phone

+98 58 3722 8634

##### 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

##### Street address

No. 70, Imam Reza Alley12 , Imam Reza Ave

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfarayen University of Medical Sciences

##### Full name of responsible person

Dr. Ali Asghar Neshat

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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 scientific inquiries

### Contact

**Name of organization / entity**  
Esfarayen University of Medical Sciences  
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Ali Abedi  
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Educator, Faculty member  
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Master  
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## Person responsible for updating data

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**Position**  
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**Latest degree**  
Master  
**Other areas of specialty/work**  
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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