

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of diaphragmatic breathing on pain, stress and vital signs of patients during dressing of tibial fracture

#### Protocol summary

2018-08-19, 1397/05/28

#### Study aim

Determining the effect of diaphragmatic breathing on the severity of pain, vital signs and stress of patients during dressing of tibial fracture

#### Design

For performing the study, the research samples placed randomized in one of the two following groups. The randomization is performed according to randomized block design. The first group: performing diaphragmatic breathing. The second group: routine actions. In the first group, the intensity of pain during dressing, stress and the vital signs of systolic pressure, diastolic pressure, pulse, and oxygen saturation before performing of diaphragmatic breathing, immediately after the intervention and 10 minutes after the intervention are measured.

#### Settings and conduct

Imam Khomeini's hospital, Sari, Mazandaran, Iran

#### Participants/Inclusion and exclusion criteria

The first dressing after tibial fracture surgery;  
communication ability

#### Intervention groups

Performing of diaphragmatic breathing

#### Main outcome variables

Pain severity during dressing; Stress; Vital signs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101108005134N11**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **prospective**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Ali Fakhr-Movahedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4192

##### Email address

Alimovi49@semums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2018-08-23, 1397/06/01

#### Expected recruitment end date

2020-04-20, 1399/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of diaphragmatic breathing on pain, stress and vital signs of patients during dressing of tibial fracture

#### Public title

The effect of diaphragmatic breathing on pain, stress and vital signs of patients during dressing of tibial fracture

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The first dressing after tibial fracture surgery  
Communication ability

##### Exclusion criteria:

Addiction Diabetes disease Injury to chest and abdomen  
Occurring crisis condition Alteration in patient status

Fracture of shaft of tibia with or without mention of  
fracture of fibula

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization is performed according to randomized  
block design

## 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

Ethical committee of Semnan university of medical  
sciences

##### Street address

Research and technology deputy, Semnan University  
of Medical Sciences, Basij Blvd.

##### City

Semnan

##### Province

Semnan

##### Postal code

35198-99951

#### Approval date

2018-07-17, 1397/04/26

#### Ethics committee reference number

IR.SEMUMS.REC.1397.113

## Health conditions studied

### 1

#### Description of health condition studied

Tibial fracture

#### ICD-10 code

S82.2

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

Before intervention, 10 and 20 minutes after dressing

#### Method of measurement

The pain numerical rating scale

### 2

#### Description

Stress

#### Timepoint

Before intervention, 10 and 20 minutes after dressing

#### Method of measurement

Stress visual analog scale

### 3

#### Description

Blood pressure

#### Timepoint

Before intervention, 10 and 20 minutes after dressing

#### Method of measurement

Aneroid sphygmomanometer

### 4

#### Description

Pulse

#### Timepoint

Before intervention, 10 and 20 minutes after dressing

#### Method of measurement

Pulse oximeter

### 5

#### Description

O2 saturation

#### Timepoint

Before intervention, 10 and 20 minutes after dressing

#### Method of measurement

Pulse oximeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Perform diaphragmatic breathing for  
10 minutes, first raising the patient's head up to 30  
degrees, and asking the patient to place his hands  
preferably on the abdomen and then first take a gentle

breath from the nose. The patient is requested to focus on the abdomen while breathing deeply, and to pay attention to the extent of the abdomen to a maximum extent so that its elevation can be seen or felt by the hands it is placed on the abdomen. Then, after a full tail, the exertion is slowly performed.

**Category**

Treatment - Other

**2****Description**

Control group: Routine action is done. First, the previous dressing is removed gently from the wound and then the wound is washed with normal saline. Finally, the new and clean dressing is fixed on the ulcer.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Dr. Misagh Shafizadeh

**Street address**

Imam Khomeini hospital, Razi St.

**City**

Sari

**Province**

Mazandaran

**Postal code**

48166-33131

**Phone**

+98 11 3304 4000

**Email**

info@emamhospital.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr Parviz Kokhaei

**Street address**

Research and technology deputy, Semnan University of Medical Sciences, Basij Blvd.

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Semnan

**Province**

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**Phone**

+98 23 3344 1022

**Email**

p\_kokha@yahoo.com

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

Yes

**Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Fakhr-Movahedi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

Nursing School, Semnan University of Medical Sciences, 5th km Damghan road

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Alimovi@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

1. The study protocol 2. The results of the study

**When the data will become available and for how long**

After termination of the study

**To whom data/document is available**

1. Faculty members 2. The clinical nurses 3. The medical and nursing students

**Under which criteria data/document could be used**

Access to data or documentation is subject to the following conditions: 1- Use in Future Studies References 2- The future studies

**From where data/document is obtainable**

Please contact Ali Fakhr-Movahedi Email: alimovi@yahoo.com

**What processes are involved for a request to access data/document**

After emailing Ali Fakhrmohahdi, email will be answered as soon as possible.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

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