

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

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48166-33131

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+98 11 3304 4000

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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

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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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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

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