

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study the Effect of Family Presence on Patient's Pain and Anxiety during Invasive Nursing Procedures at the Emergency Department

Protocol summary

Study aim

Study the effect of family presence on patient's pain and anxiety during invasive nursing procedures at the emergency department.

Design

Non-randomized clinical trial with control group. Sample size is 70 persons.

Settings and conduct

This study will be performed in an emergency department. Will carry out an invasive nursing procedure for experimental group in presence of family and for control group without family presence. Then mean pain and anxiety score before and after the invasive nursing procedure will be compared between experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being 18-75 years old, Being open to communication and cooperation, Undergoing an invasive nursing procedure. Exclusion criteria: Without visitor. Having anxiety and psychological disorders. Using of sedative and hypnotic drugs. Drug addiction. Having severe pain. Taking pain killer.

Intervention groups

Intervention group: The invasive nursing procedure (including: peripheral intravenous cannulation, intramuscular injection or venipuncture) will be performed with family member presence (who is chosen by the patient). The type of invasive nursing procedures and relationship accompanying person with the patient will be written in the demographic and medical information form. Control group: The invasive nursing procedure will be performed without family presence. In other words, family members will be taken out by researcher before invasive nursing procedure.

Main outcome variables

Pain and anxiety score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039190N1**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **prospective**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

Parvin Abdi gheslaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4832 5867

Email address

parvinabdinurse1721369@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Effect of Family Presence on Patient's Pain and Anxiety during Invasive Nursing Procedures at the Emergency Department

Public title

Study the Effect of Family Presence on Patient's Pain and Anxiety during Invasive Nursing Procedures at the Emergency Department

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being 18-65 years old Being open to communication and cooperation Undergoing an invasive nursing procedure

Exclusion criteria:

Without visitor Having anxiety and psychological disorders Using of sedative and hypnotic drugs Drug addiction Having severe pain Taking pain killer

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Shahid Beheshti university of medical sciences

Street address

Vali Asr Ave., Niayesh Complex., nursing shoole of Shahid Beheshti university of Medical Sciences.,Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.SBMU.PHNM.1396.964

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

2**Description of health condition studied**

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Pain score according to Visual Analogue Scale

Timepoint

After the invasive nursing procedure

Method of measurement

Visual Analogue Scale

2**Description**

State anxiety score according to Spielberger anxiety inventory

Timepoint

Before and after the invasive nursing procedure

Method of measurement

Spielberger anxiety inventory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The invasive nursing procedure (including: peripheral intravenous cannulation, intramuscular injection or venipuncture) will be performed whit family member presence (who is chosen by the patient). The type of invasive nursing procedures and relationship accompanying person with the patient will be written in the demographic and medical information form.

Category

Other

2

Description

Control group: The invasive nursing procedure will be performed without family presence. In other words, family members will be taken out by researcher before invasive nursing procedure.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Moaven hospital in Sahneh

Full name of responsible person

Ziba Barzabadi Farahani

Street address

Vali Asr Ave., Niayesh Complex., Nursing school of Shahid Beheshti university of medical sciences., Tehran., Iran

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zibafarahani717@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziaei

Street address

Shahid Beheshti university of medical sciences, next to the Taleghani hospital, Shahid Arabi street, Yemen street, Shahid Chamran high way, Tehran, Iran

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvin Abdi Gheshlaghi

Position

Master of nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ziba Barzabadi Farahani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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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