

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of preoperative visitation by operating room staff on agitation among patients with ventral hernia

Protocol summary

Study aim

Determining the effect of preoperative visitation by operating room staff on agitation among patients suffering from ventral hernia

Design

Randomized clinical trial with control group, Each group consists of 35 patients, Without blinding

Settings and conduct

After selecting patients from surgical ward of Imam Hossein Hospital in Shahroud, each patient in the intervention group will be met by a researcher (operating room staff) before surgery. After transferring the patient to the operating room, the researcher (operating room staff) will again visit the patient and remain with the patient until induction of anesthesia. After transferring the patient to recovery room, the agitation of the patients will be measured in both groups using the Richmond scale, every 15 minutes up to 60 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective surgery for ventral hernia (inguinal, femoral and umbilical hernia), Age group of 15-65 years old, Ability to speak in Persian. Non inclusion criteria: Having previous surgery experience, Addiction to analgesic drugs, Medical and paramedical personnel, Having a known psychological disorder based on a physician opinion

Intervention groups

Intervention group: Before surgery and after transferring the patient to the operating room, the patient will be met by a researcher and the researcher will remain with the patient until induction of anesthesia. Control group: will not receive the intervention and will only receive routine care.

Main outcome variables

Agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100114003064N15**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

bagheri@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of preoperative visitation by operating room staff on agitation among patients with

ventral hernia

Public title
preoperative visit and postoperative agitation

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Elective surgery for ventral hernia (inguinal, femoral and umbilical hernia) Age group of 15-65 years Ability to speak in Persian
Exclusion criteria:
Having previous surgery experience Addiction to analgesic drugs Medical and paramedical personnel Having a known psychological disorder based on a physician opinion

Age
From **15 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)
Randomized

Randomization description
Closed envelopes will be used to hide the random allocation. Based on the blocks of size 4, provided by the statistics consultant, a table of seventy "A" and "B" letters will be prepared. To hide the random assignment, each of these letters will be placed in an envelope, respectively, and each envelope, will be numbered based on the order that is present in the initial table. After selecting each eligible patient, the patient's envelope will be opened and the patient is assigned to one of two groups based on the letters in the envelope.

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 Shahroud University of Medical Sciences

Street address

Hafte-Tir Sq.,

City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2019-03-11, 1397/12/20
Ethics committee reference number
IR.SHMU.REC.1397.236

Health conditions studied

1

Description of health condition studied

Ventral hernia

ICD-10 code

K43

ICD-10 code description

Ventral hernia

Primary outcomes

1

Description

Agitation

Timepoint

Every 15 minutes after surgery up to 60 minutes

Method of measurement

Richmond Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before surgery, the patient will be met by a researcher (operating room staff) in the surgical ward, and after transferring the patient to the operating room, the researcher (operating room staff) will again visit the patient and remain with patient until induction of anesthesia.

Category

Prevention

2

Description

The control group will not receive the intervention and will only receive routine care in the surgery ward and operating room.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr.Hossein Bagheri

Street address

At the end of the 28 Metri Touhidi, Imam Khomeini street

City

Shahroud

Province

Semnan

Postal code

3613773955

Phone

+98 23 3234 2000

Email

bagheri@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Hassan Emamian

Street address

Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

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

No

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossien Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 5054

Email

bagheri@shmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

bagheri@shmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossien Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahrud University of Medical Sciences, Hafte-Tir
Sq., Tehran Street

City

Shahrud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 5054

Email

bagheri@shmu.ac.ir

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