Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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3613773955

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+98 23 3234 2000

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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

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3614773947

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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

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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