Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of hand and foot massages by nurse and concomitant of patient on pain severity in abdominal surgeries

Protocol summary

Study aim

Comparison of the effect of hand and foot massage by nurse and patient along the severity of pain after abdominal surgery

Design

Sampling is done easy And qualified patients entered the study and then randomly assigned using computer software in one of the groups 1) Massage by nurse, 2) Massage by patient and 3) Control group.

Settings and conduct

After surgery and after entering patients into the department and ensuring complete vigilance (passing at least 6 hours of entering the department), Having the criteria for entering and preparing the patient for admission to the massage They will be included in the study if they are required to participate in the study on the basis of entry and exit criteria. The demographic data of all patients participating in the study, including age, gender, marital status, occupation, educational level and history of massage therapy, will be recorded in the personal information form. In the group that is given by the massage, the education of the patient and the proportion of the patient with the patient It will also be recorded. Before the intervention, all patients will be evaluated by a numerical grading scale to measure pain intensity. This tool is a 10-degree scale line in the range of 10-0 In such a way that the zero score, the painless state, and the odds, show the worst pain possible The patient is asked to determine the severity of her pain on the instrument.

Participants/Inclusion and exclusion criteria

Abdominal surgery, Full postoperative alertness, Satisfaction to participate in the research project

Intervention groups

Researcher massage, massage by patients' families

Main outcome variables

Intensity of pain Number of breaths Systolic blood pressure Diastolic blood pressure Number of pulses Satisfaction level of massage Satisfaction with pain control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111224008505N48**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-14, 1397/10/24**
Update count: **0**

Registration date

2019-01-14, 1397/10/24

Registrant information

Name

Seyed Saeed Najafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1727 7445

Email address

najafisa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effect of hand and foot massages by nurse and concomitant of patient on pain severity in abdominal surgeries

Public title
the effect of hand and foot massages on pain severity in abdominal surgeries

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Abdominal surgery (cholecystectomy, appendicitis) with general anesthesia; Age between 18 and 60 years; Full vigilance after surgery; Lack of drug and alcohol addiction; Not having sensory and motor disorders; The absence of mental illness (which prevents proper communication and mutual understanding); Lack of muscular and articular diseases;

Exclusion criteria:
Unwillingness to continue cooperation; Sensitivity to touch and inability of the individual to tolerate massage; Known for cardiovascular disease; Having a wound or burn in the area where the massage is to be done; Sensitization and skin diseases in the area of the hand that prevent the massage; History of Massage Therapy; Patient with diabetes; laparoscopy;

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Examples of eligible entry criteria will be selected, then by random assignment of a block in the three groups of massage by the researcher, massages will be shared with the patient and the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, measurement and recording of pain severity and doses of pain killer drugs will be done a person who is blinded to the patient allocation groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz, 7th floor, Shiity of Medical Sciencraz Universes, Zand Blvd.,

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2018-07-31, 1397/05/09

Ethics committee reference number
ir.sums.rec.1397.601

Health conditions studied

1

Description of health condition studied
Severity of surgical pain

ICD-10 code
R10

ICD-10 code description
Abdominal and pelvic pain

Primary outcomes

1

Description
Intensity of pain

Timepoint
Before and 6 hours after surgery

Method of measurement
Numerical grading scale to measure pain severity

Secondary outcomes

1

Description
severity of pain assess by Visual Analogue Scale (VAS)

Timepoint
preoperative and 6 hours after operation

Method of measurement
severity of pain will be measured by a ruler numerated from zero to ten. Accordingly scores of one to three , four to seven, and eight to ten represent mild, moderate and severe pain, respectively.

Intervention groups

1

Description
Intervention group: Massage group by researcher-For 30 minutes,Twice, Before surgery and 6 hours after surgery
Category
Treatment - Other

2

Description
Intervention group: Massage by patients' families-For 30 minutes,Twice, Before surgery and 6 hours after surgery
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals of Shahid Rajaee Gachsaran and Besat Hospital of Gachsaran Oil Company
Full name of responsible person
Ebrahim Ebadi
Street address
Kohkiloyeh and Boyer Ahmad - Gachsaran Blvd. Shahid Tondoogan - Besat Hospital
City
Gachsaran
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7134814336
Phone
+98 74 3222 5712
Email
info@piho.ir
Web page address
http://gch.piho.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ghasemi Yones
Street address
7th floor, Shiraz University of Medical Sciences central building, Zand Blvd., Shiraz, Iran
City
Shiraz
Province
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Postal code
1978_71345
Phone
+98 71 3230 5410
Fax
+98 71 3212 2430
Email
hashemib@sums.ac.ir
Web page address
http://research.sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Saeed Najafi
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Thesis dissertation And article
When the data will become available and for how long
Unlimited
To whom data/document is available
Student and supervisor
Under which criteria data/document could be used
Preparing thesis and article
From where data/document is obtainable
Student and supervisor
What processes are involved for a request to access data/document
Official and written permission of student and supervisor
Comments