

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 Rajaei Gachsaran and Besat Hospital of Gachsaran Oil Company

Full name of responsible person

Ebrahim Ebadi

Street address

Kohkiluyeh and Boyer Ahmad - Gachsaran Blvd. Shahid Tondoogan - Besat Hospital

City

Gachsaran

Province

Kohgiluyeh-va-Boyerahmad

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

Fars

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

School of Nursing and Midwifery, Namazi Square, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71936 -13119

Phone

+98 71 3647 4254

Email

najafisa@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Saeed Najafi

Position

Faculty member

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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)**

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