Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of hand massage on anxiety in ophthalmology surgery using local anesthesia

Protocol summary

Summary

Anxiety is common disorders of patients especially before surgery. If anxiety is not controlled, can cause psychological and physiological reactions and will affect the process of surgery and recovery. Therefore, this study examined effect of hand massage on anxiety in ophthalmology surgery using local anesthesia. In this experimental study, 52 patients who have been ophthalmology surgery using local anesthesia were studied. Patients were assigned randomly to an experimental group (hands massage before surgery, n= 27 patients) and control group (no hand massage, n=25 patients). Patients in the Experimental group had a hand massage for 5 minutes before surgery. Two researchers trained by stroke and scrubbing method performed all the massages. In stroke and scrubbing method, olive oil is applied to the patients' hands and each hand is massaged just before surgery for 5 minutes (each hand 2 minutes and 30 seconds). Massage was including a series of scrubbing movements down from the wrist to the fingers using large circular stretching strokes, and stroke movements in palm and back of hands. In addition, palpation, stretching, and circular range of motion were done on the fingers. All study parameters(Anxiety level by Eshpil Berger standard questionnaire, blood pressure, pulse rate and respiratory rate) were measured at the 2 time in both group: before and after the experimental group received the hand massage. Data was analyzed by chi-square, independent samples T test and paired T test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107056955N1**
Registration date: **2011-07-27, 1390/05/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-07-27, 1390/05/05

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hand massage on anxiety in ophthalmology surgery using local anesthesia

Public title

Effect of hand massage on anxiety in ophthalmology surgery using local anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 20-60 years old; pharmacological surgery using local anesthesia by the some surgeon using the same technique performed between 9-12AM. Exclusion criteria: hormone therapy; sedative before surgery; were diagnosed as having a disease that elevates blood level of Epinephrine, Cortisol and blood sugar; had hands with injury, erratum, edema and pain in hands; psychological disorders or receiving psychological drugs; uncontrolled cardiovascular diseases.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Gangafrooz Ave, Babol, Iran

City

Babol

Postal code

Approval date

2010-01-05, 1388/10/15

Ethics committee reference number

88274412

Health conditions studied

1

Description of health condition studied

Eye surgery

ICD-10 code

H00-H59

ICD-10 code description

Diseases of the eye and adnexa

2

Description of health condition studied

Complication of local anesthesia

ICD-10 code

y40-y84

ICD-10 code description

Surgical and other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Anxiety levels

Timepoint

Before massage, after massage

Method of measurement

Eshpil Berger standard questionnaire

Secondary outcomes

1

Description

Vital signs (blood pressure, pulse rate and respiratory rate)

Timepoint

Before massage, after massage

Method of measurement

Digital machine and observation

Intervention groups

1

Description

Patients in the Experimental group had a hand massage for 5 minutes before surgery. Two researchers trained by stroke and scrubbing method performed all the massages. In stroke and scrubbing method, olive oil is applied to the patients' hands and each hand is massaged just before surgery for 5 minutes (each hand 2 minutes and 30 seconds). Massage was including a series of scrubbing movements down from the wrist to the fingers using large circular stretching strokes, and stroke movements in palm and back of hands. In addition, palpation, stretching, and circular range of motion were done on the fingers.

Category

Treatment - Other

2

Description
No massage or other treatment
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hefdah Shahrivar Hospital of Amol
Full name of responsible person
Sima Khazaeinajad
Street address
Operation room, Hefdah Shahrivar Hospital, Hefdah Shahrivar Ave, Amol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences
Full name of responsible person
Dr. Amrollah Mostafazadeh
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Vice chancellor for research, Babol University of Medical Sciences, Gangafrooz ave, Babol
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty