

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

###### Name

Roghieh Nazari

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 4422 1919

###### Email address

r.nazari@mubabol.ac.ir

##### 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, Gangafruz 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

##### City

Amol

## 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

##### Street address

Vice chancellor for research, Babol University of Medical Sciences, Gangafrooz ave, Babol

##### City

Babol

#### 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

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Roghieh Nazari

##### Position

Faculty member

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

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Master of Science in Nursing

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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*