# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison of the effect of foot reflexology massage with and without black seed oil on pain, nausea and vomiting, hemodynamic indicators and recovery quality of elective caesarean section patients under spinal anesthesia.

## Protocol summary

**Study aim**
The effectiveness of these non-pharmacological methods in controlling pain, nausea and vomiting, hemodynamic indicators and the quality of recovery after surgery

**Design**
A parallel randomized clinical trial with a control group, on 102 patients, used Block randomization for randomization.

**Settings and conduct**
Place of performance: Imam Ali (a.s.) educational and therapeutic hospital in the surgical and operating room departments. Intervention group with black seed oil: pressure on three sensitive points the solar plexus, pituitary gland and heart with the thumb. This pressure is to the extent that the upper third of the researcher's thumb turns white, and then massage is given to all the soles of the feet in a circular manner. Intervention group with baby oil: same as the previous group with the difference in the use of baby oil Control group, touch without pressure in the form of gentle superficial massage at the same point Blinding patients, to separate patients in a private environment from screens, to isolate patients

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:Pregnancy term - 18-45 years old - no touch - no sensitivity to touch - no drug addiction - no problems in speech, hearing and vision - elective caesarean sectionExclusion criteria: spinal contraindications - preeclampsia - emergency cesarean

**Intervention groups**
Intervention group with black seed oil pressure on three sensitive points, solar plexus, pituitary gland, and heart, with the thumb. intervention group with baby oil: pressure on three sensitive points, which are the solar plexus, pituitary gland, and heart, with the thumb. Control group, touch without pressure

**Main outcome variables**
pain, severity of nausea and vomiting, hemodynamic indicators, quality of recovery.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230208057364N1**
Registration date: **2023-03-10, 1401/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-10, 1401/12/19**
Update count: **0**

**Registration date**
2023-03-10, 1401/12/19

**Registrant information**

**Name**
Maryam Pouramanyanhir

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 11 4415 1828

**Email address**
pouramanyanmaryam@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-02-19, 1401/11/30

**Expected recruitment end date**
2023-07-21, 1402/04/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the effect of foot reflexology massage with and without black seed oil on pain, nausea and vomiting, hemodynamic indicators and recovery quality of elective caesarean section patients under spinal anesthesia.

**Public title**
Comparison of the effect of massage with and without black seed oil on pain, nausea and vomiting of caesarean section patients using lumbar anesthesia.
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Term of pregnancy Being 18-45 years old Not having a lesion at the place of application of touch Insensitivity to touch or massage No drug addiction Having no problems in speech, hearing and vision Not having known mental disorders Elective caesarean section Not having spinal restrictions No medical problems and no midwifery problems after surgery such as heavy bleeding Not having crises such as a history of divorce, loss of loved ones and immigration in the last 6 months
**Exclusion criteria:**
The presence of spinal contraindications Presence of preeclampsia Emergency caesarean section Conversion of spinal anesthesia to general anesthesia for any reason Hemodynamic instability Lack of consent to participate in the research Migration Divorce
**Age**
From **18 years** old to **45 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **102**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Parallel randomized clinical trial - patients are continuously referred and then entered into the study based on the type of random allocation. This research will be allocated to three groups of foot reflex massage with oil (O), foot reflex massage without oil (W), control (C) or routine before starting the study by block randomization method. The blocks of this research are 6 (OO, WW, CC) and 27 states will be created. First, the possible states of these 6 letters inside the blocks will be determined, and then the numbers of the blocks will be determined in a simple random manner using a table of random numbers. In this way, the type of intervention based on the desired letters will be determined with the number of each patient and will be kept in a master sheet, and finally, the intervention number of each patient will be inserted on a sheet when visiting and the type of intervention will be known at that moment (entry number The patient records are entered on the envelope and the type of intervention or control is specified inside the envelope. Gradually, according to the presence of eligible patients, the corresponding envelope is returned, and the type of intervention that is inside the non-transparent envelope is specified, and the desired technique will be done.)
**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 Mazandaran University of Medical Sciences
**Street address**
Serah Joibar, the beginning of Vali Asr Highway (AJ), the headquarters of Mazandaran University of Medical Sciences and Health Services
**City**
Amol
**Province**
Mazandaran
**Postal code**
۳۳۹۷۱-۴۸۱۵۷
**Approval date**
2023-02-14, 1401/11/25
**Ethics committee reference number**
IR.MAZUMS.REC.1401.500

## Health conditions studied

### 1

**Description of health condition studied**
Nausea and vomiting - pain - duration of discharge from recovery - hemodynamic indicators - digestive index (constipation) - shaving - urinary output - reflex massage - cesarean section - spinal anesthesia - black seed
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Determining the postoperative pain level of patients at the time of discharge from recovery, 24 and 48 hours after surgery in caesarean section patients in the reflex massage groups with and without black seed oil and their control group, this scale was a ten-centimeter horizontal ruler ranging from zero to It was graded ten. The number zero indicated the absence of pain symptoms and the number ten meant the maximum intensity of the desired symptoms.

**Timepoint**
Post-operative pain level, recovery time, 24 and 48 hours after the operation and after reflexology massage with and without black seed oil.

**Method of measurement**
Visual analogue scale is used to measure the pain of the operation site

### 2

**Description**
Determining the severity of nausea in patients during surgery, after surgery and 24 hours after surgery in caesarean section patients of reflexology massage groups with and without black seed oil and their control group, the visual scale for registering the severity of nausea is a self-report scale. Nausea with a grade above 7 is classified as severe, between 3.5 and 7 as moderate, and less than 3.5 as mild.

**Timepoint**
Determining the severity of nausea in patients during surgery, after surgery and 24 hours after surgery and after reflexology massage with and without black seed oil.

**Method of measurement**
Visual scale

### 3

**Description**
To evaluate the amount of vomiting, counting the number of times vomiting is used. Vomiting more than 5 times is defined as severe, between 3-5 times as moderate and less than 3 times as mild.

**Timepoint**
The amount of nausea and vomiting is measured after the intervention, during the operation, after the operation and 24 hours after the operation.

**Method of measurement**
Visual scale

### 4

**Description**
Measurement of hemodynamic indicators (systolic and diastolic blood pressure, pulse and spo2)

**Timepoint**
Before the operation, after the birth of the baby and after the last suture in the cesarean section

**Method of measurement**
Monitoring device

### 5

**Description**
Measuring the duration of recovery in two time periods

**Timepoint**
The moment of entering recovery and the time of discharge from recovery after applying massage

**Method of measurement**
It is recorded in minutes

## Secondary outcomes

### 1

**Description**
Determining postoperative headache in patients

**Timepoint**
Recovery time, 24 and 48 hours after the operation

**Method of measurement**
The measurement of headache is a visual analogue scale, this scale was a ten-centimeter horizontal ruler graded from zero to ten. The number zero indicates the absence of pain symptoms and the number ten means the maximum intensity of the symptoms

### 2

**Description**
2. Determining shivering of patients

**Timepoint**
During recovery

**Method of measurement**
By observing the patient during recovery and at four levels, the absence of muscle tremors is scored as zero, straightening of hair, peripheral cyanosis: 1, visible muscle tremors in one muscle group: 2, visible muscle tremors in more than one muscle group: 3 and muscle tremors. Visible in all the muscles of the body: 4

### 3

**Description**
6. Digestive index (constipation)

**Timepoint**
24 and 48 hours after the operation

**Method of measurement**
The checklist of digestive complications is constipation. Constipation by asking the patient and the information entered in the patient's file in terms of passing gas, straining, flatulence, abdominal pain, firm consistency, lack of defecation.

### 4

**Description**
Determination of urinary output of patients

**Timepoint**
During operation, exit from recovery and 12 hours later in patients

**Method of measurement**

Urinary output is measured by a questionnaire. After the implementation of foot reflex massage interventions with and without black seed oil through the inserted urinary catheter, he will do it by observing the urine bag and the patient's file.

## Intervention groups

### 1

**Description**

Intervention group: The first intervention group: The intervention group (reflex massage of the soles of the feet): pressure on three sensitive points, which are the solar plexus, pituitary gland, and heart, with the thumb. This pressure is to the extent that the upper third of the researcher's thumb turns white, and then massage is given to all the soles of the feet in a circular manner. The meaning of massage in this study is a 20-minute foot massage (10 minutes after the patient is stabilized on the operating bed and 10 minutes during recovery and 3 seconds of rest for every 2 minutes of direct pressure). The movement of the thumb or other fingers is circular clockwise and continuously on the reflective points without breaking the contact with the skin and will be done with black seed oil (Barij company).Before the intervention, in order for the researcher's hand to have more contact with the massage area, the patient's feet were first cleaned using a wet towel, then the researcher performed reflex foot massage without using cream or emollient with black seed oil in the intervention group for 20 minutes (10 minutes for each foot) and it is done first on the left foot and then on the right foot. If there is edema in the client's leg, more pressure is applied to perform the techniques.

**Category**

Prevention

### 2

**Description**

Intervention group: The second intervention group: reflex massage of the soles of the feet: pressure on three sensitive points, which are the solar plexus, pituitary gland, and heart, with the thumb. This pressure is to the extent that the upper third of the researcher's thumb turns white, and then massage is given to all the soles of the feet in a circular manner. The meaning of massage in this study is a 20-minute foot massage (10 minutes after the patient is stabilized on the operating bed and 10 minutes during recovery and 3 seconds of rest for every 2 minutes of direct pressure). The movement of the thumb or other fingers is circular in the clockwise direction and continuously on the reflex points without breaking the contact with the skin and will be done with baby oil (Firooz Company). First, the patient's feet were cleaned using a wet towel, then the researcher performed a reflex foot massage without using cream or softener with black seed oil in the intervention group for 20 minutes (10 minutes on each foot, first on the left foot and then on the right foot). will be If there is edema in the client's leg, more pressure is applied to perform the techniques.

**Category**

Prevention

### 3

**Description**

Control group: The touch without pressure will be applied with the same pattern as the sole reflex massage groups as a superficial and gentle massage at the same point.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam Ali (AS) Hospital

**Full name of responsible person**
Dr. Alireza Yahyai Shahandashti

**Street address**
Sheikh Fazlullah Nouri Street, km 2, Chamestan Road, Imam Ali Hospital

**City**
Amol

**Province**
Mazandaran

**Postal code**
46171 41497

**Phone**
+98 11 4426 4661

**Email**
EmamAlihospital@yahoo.com

**Web page address**
https://bankpezeshkan.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Dr. Pedram Ebrahimnejad

**Street address**
No.2, Third Floor,Mazandaran University of Medical Sciences and Health Services Building,Research and Technology Vice-Chancellor,Moalem Square

**City**
Sari

**Province**
Mazandaran

**Postal code**
4817893134

**Phone**
+98 11 3448 4874

**Email**
jmums@mazums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Mazandaran 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**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Dr. Ebrahim Nasiri

**Position**
Associate Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

**Street address**
Kilometer 17 of Farah Abad Road, Prophet Azam University Complex, Faculty of Paramedicine

**City**
Sari

**Province**
Mazandaran

**Postal code**
7771

**Phone**
+98 11 3354 2469

**Fax**
+98 11 3354 2469

**Email**
rezanf2002@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Dr. Ebrahim Nasiri

**Position**
Associate Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

**Street address**
Prophet Azam University Complex, Paramedical FacultyKm 17 Khazar Abad Road,Khazar Square

**City**
Sari

**Province**
Mazandaran

**Postal code**
7771

**Phone**
+98 11 3354 2469

**Email**
rezanf2002@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Dr. Ebrahim Nasiri

**Position**
Associate Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

**Street address**
Khazar Square, Km 17 Khazar Abad Road, Prophet Azam University Complex, Paramedical Faculty

**City**
Sari

**Province**
Mazandaran

**Postal code**
7771

**Phone**
+98 11 3354 2469

**Email**
rezanf2002@yahoo.com

## 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