

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparing the effect of Melissa officinalis tea versus Matricaria Chamomilla tea on pain intensity, anxiety, and satisfaction with pain management in patients undergoing lower limb orthopedic surgery

#### Protocol summary

##### Study aim

comparing the effect of matricaria chamomilla tea and melissa officinalis tea on pain intensity, anxiety and satisfaction with pain management in patients undergoing lower limb orthopaedic surgery

##### Design

in this study, 96 patients undergoing lower limb orthopaedic surgery having inclusion criteria will choose. participants will allocate to the three study group (chmomile, melissa officinalis, control) with randomization blocking.

##### Settings and conduct

This study is randomized controled trial that will done in ayatollah kashani educational hospital. After obtaining informed consent form, participants will allocate to three study group with randomization blocking method. First, pain intensity, anxiety and satisfaction with pain management will evaluate with standard questionnaire. then, matricaria chamomilla tea will prescribe for matricaria chamomilla group, melissa officinalis tea will prescribe for melissa officinalis group, and black tea will prescribe for control group. After all interventions, before and after intervention mean score of each variable before compared in each group and between the three study groups.

##### Participants/Inclusion and exclusion criteria

patient undergoing lower limb orthopaedic surgery, willingness to participate in the study, normal gag reflex after surgery, age 15 and over, moderate and sever pain intensity (point 4 and above in VAS scale), orientation to time, place and person, no prescription of anxiolytic drug, Absence of underlying disease causing pain and anxiety, lack of history of sensitivity to Melissa officinalis and Matricaria Chamomilla, no prescription of warffarin, no prescription benzodiazepines and sedative drugs, lack of asthma, normal kidney and liver function

##### Intervention groups

Melissa officinalis group: for this group, melissa officinalis tea bag produced by Golnoosh Darband company will beprescribed. Each tea bag contains 1g melissa officinalis. melissa officinalis tea will prescribe three times per day in 6 AM, 2 PM and 10 PM. Each time, 1 tea bag containing melissa officinalis will put in 150 cc of boiling water and then consumed by the patient.

Matricaria chamomilla group: for this group, matricaria chamomilla tea bag produced by Golnoosh Darband company will be prescribed. Each tea bag contains 1g matricaria chamomilla. Since time of intervettions mus be equal in all three groups, therefore, matricaria chamomilla tea will prescribe 3 times a day in similar times with melissa officinals group. Control group: for this group, black tea will prescribe at above mentioned times.

##### Main outcome variables

pain intensity anxiety satisfaction with pain management

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170122032101N2**

Registration date: **2018-01-16, 1396/10/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

##### Registration date

2018-01-16, 1396/10/26

##### Registrant information

##### Name

Haydeh Heidari

##### Name of organization / entity

Medical University

##### Country

Iran (Islamic Republic of)

**Phone**

+98 33346699

**Email address**

heidari.h@skums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-01-05, 1396/10/15

**Expected recruitment end date**

2018-04-04, 1397/01/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of Melissa officinalis tea versus Matricaria Chamomilla tea on pain intensity, anxiety, and satisfaction with pain management in patients undergoing lower limb orthopedic surgery

**Public title**

Comparing the effect of Melissa officinalis tea versus Matricaria Chamomilla tea on pain intensity, anxiety, and satisfaction with pain management

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

patient undergoing lower limb orthopaedic surgery willingness to participate in the study normal gag reflex after surgery age 15 and over moderate and sever pain intensity (point 4 and above in VAS scale) orientation to time, place and person no prescription of anxiolytic drug Absence of underlying disease causing pain and anxiety lack of history of sensitivity to Melissa officinalis and Matricaria Chamomilla no prescription of warffarin no prescription benzodiazepines and sedative drugs lack of asthma normal kidney and liver function

**Exclusion criteria:**

pregnant women children

**Age**

From 15 years old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 96

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

the sample for this study is 96 patients which will allocate to three groups (chamomile, melissa officinalis,

control) with blocking randomization method. for randomization, 32 block with capacity of 3 patients will be made. blocking will be based on demographic data (age group, sex, addiction). each patient is first allocated to a block based on his or her demographic data, then, based on drawing a letter, the patients allocates to one of the study groups. allocation of second and third patinet of each block to study groups, will be based on previos patints on that block.

**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 shahre-kord University of Medical Sciences

**Street address**

Ayatollah kashani blvd

**City**

shahre-kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Approval date**

2017-09-17, 1396/06/26

**Ethics committee reference number**

IR.SKUMS.REC.156

**Health conditions studied**

**1**

**Description of health condition studied**

lower limb orthopaedic surgery

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

pain intensity score in visual analogue scale

**Timepoint**

before interventions and 30 minutes after prescription of each dose

**Method of measurement**

visual analogue scale

## 2

### **Description**

anxiety score in Spielberger state anxiety inventory

### **Timepoint**

before interventions and 30 minutes after prescription of each dose

### **Method of measurement**

Spielberger state anxiety inventory

## 3

### **Description**

satisfaction with pain management score in satisfaction with pain management questionnaire

### **Timepoint**

before interventions and 30 minutes after prescription of each dose

### **Method of measurement**

satisfaction with pain management questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: melissa officinalis group: for this group, melissa officinalis tea bag produced by golnoosh darband company will prescribe. each tea bag contains 1g melissa officinalis. melissa officinalis tea will prescribe three times per day in 6AM, 2PM AND 10PM. each time, 1 tea bag containing melissa officinalis will put in 150 cc of boiling wate and then consumed by the patient.

#### **Category**

Other

### 2

#### **Description**

Intervention group: matricaria chamomilla group: for this group, matricaria chamomilla tea bag produced by golnoosh darband company will prescribe. each tea bag contains 1g matricaria chamomilla. since time of intervations mus be eaul in all three groups, therefore, matricaria chamomilla tea will prescribe 3 times a day in similar times with melissa officinals group.

#### **Category**

Other

### 3

#### **Description**

Control group: or this group, black tea will prescribe at above mentioned times.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

ayatollah kashani hospital

##### **Full name of responsible person**

haydeh heydari

##### **Street address**

ayatollah kashani hospital, nurse ave

##### **City**

shahre-kord

##### **Province**

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##### **Postal code**

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+98 38 3226 4825

##### **Email**

heidari.h@skums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahre-kord University of Medical Sciences

##### **Full name of responsible person**

dr kamal solati

##### **Street address**

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##### **Email**

kamal\_solati@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Reza saidi

**Position**

دانشجوی کارشناسی ارشد پرستاری داخلی جراحی

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

haydeh heydari

**Position**

associate professor

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Ph.D.

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Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**City**

shahre-kord

**Province**

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**Postal code**

8871633411

**Phone**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there are no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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