Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 surgury

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 questionaire. 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 intervetions mus be eqaual 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 surgury

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 prescribtion 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 prescribtion of each dose
Method of measurement
Spielberger state anxiety inventory

3

Description
satisfaction with pain management score in satisfaction with pain management questionaire
Timepoint
before interventions and 30 minutes after prescribtion of each dose
Method of measurement
satisfaction with pain management questionaire

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 intervetions mus be eaual 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
Chahar-Mahal-va-Bakhtiari
Postal code
8816758915
Phone
+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
Ayatollal kashani blvd
City
shahre-kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816758915
Phone
+98 38 3333 0061
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

Street address
nursing faculty, shahrelord university of medical sciences, rahmatiyeh

City
shahre-kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8871633411

Phone
+98 38 3334 6714

Email
saidi.reza@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
haydeh heidari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
nursing faculty, shahrekord university of medical sciences, rahmatiyeh

City
shahre-kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8871633411

Phone
+98 38 3333 5648

Email
heidari.h@skums.ac.ir

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

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing Faculty, shahrekord university of medical sciences, rahmatiyeh

City
Share-kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3333 5648

Fax

Email
Heidari.h@skums.ac.ir

Web page address

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