Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the efficacy and safety of Glycyrrhiza glabra and zingiber officinale in controlling pain symptoms in patients after Total Knee Arthroplasty(TKA)

Protocol summary

Study aim

Overall Objective: To evaluate the function and improve pain in patients after TKA surgery and provide appropriate oral treatment with fewer side effects and better performance than conventional NSAIDs. Minor goals: 1- Comparing the effect of licorice and ginger combination with diclofenac drug in controlling patients' pain after ¡omplete knee replacement based on VAS. 2- Comparison of the effect of licorice and ginger combination with diclofenac on inflammatory indicators (IL-6 and TNF-α) in patients after knee replacement surgery. 3- Comparison of the effect of licorice and ginger combination with diclofenac drug on patients' quality of life after complete knee replacement based on cop

Design

Randomised, superiority, parallel group trial with blinded outcome assessment.The rand function of the Excel software was used for randomization.

Settings and conduct

The study will be performed at Baqiyatallah Hospital. We will use Excel software and rand function to prepare random arrangements. The created files will be stored with the study epidemiologist during the production process of the random chain and its results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients who are candidates for complete joint replacement will be examined after surgery and discharge from the hospital. 2) informed consent form will be completed by the patient or the patient's supervisor to participate in the study. Exclusion criteria: 1) Inflammatory underlying disease such as rheumatoid arthritis 2) Drug addiction 3) Smoking

Intervention groups

Both groups will receive diclofenac medication.The intervention group will receive 500 mg of licorice and ginger herbal composition every 12 hours for 8 weeks, and the placebo group 500 mg herbal every 12 hours .

Main outcome variables

Pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N62**
Registration date: **2020-07-02, 1399/04/12**
Registration timing: **prospective**

Last update: **2020-07-02, 1399/04/12**
Update count: **0**

Registration date

2020-07-02, 1399/04/12

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of Glycyrrhiza glabra and zingiber officinale in controlling pain symptoms in patients after Total Knee Arthroplasty(TKA)

Public title

The effect of licorice and ginger herbal composition on controlling patients' pain symptoms after knee joint replacement surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are candidates for complete knee replacement after surgery and hospital discharge

Exclusion criteria:

Inflammatory underlying disease such as rheumatoid arthritis Drug addiction smoking

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Block Randomization method will be used using four and six blocks with random order. We will use Excel software and rand function to prepare random arrangements. The created files will be stored with the study epidemiologist during the production process of the random chain and its results.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Concealment A four-digit numeric code will be assigned to each of the random loop loops. The chain is generated centrally through a responsible person using a phone call or through a website The Interactive Web Response System will be dedicated to the study centers. In this way, each of the centers will be given one or more usernames and passwords to enter the website through it. Upon arrival, the patient will receive the initial information and then, to ensure that he or she has the consent and the conditions to enter the study, the randomization code will be assigned to him / her based on a predetermined random chain. Blinding This is a triple blind study and a placebo drug was designed for it, which is completely compatible with the body in terms of safety and has no side effects.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah Hospital, Mollasadra St, Vanak Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-03-13, 1398/12/23

Ethics committee reference number

IR.BMSU.BAQ.REC.1398.047

Health conditions studied

1

Description of health condition studied

Osteoarthritis, Total knee arthroplasty (TKA), Pain after surgery

ICD-10 code

M17.10

ICD-10 code description

Unilateral primary osteoarthritis, unspecified knee

Primary outcomes

1

Description

Comparison of the effect of different doses of licorice and ginger herbal composition in one group and diclofenac drug in the second group

Timepoint

Before the intervention, and 8, 12 and 24 hours after consuming the herbal combination, licorice and ginger, every 12 hours to 8 weeks

Method of measurement

The pain VAS is a unidimensional measure of pain intensity

Secondary outcomes

1

Description
post-intervention Quality of life score
Timepoint
Up to 28 weeks after the intervention
Method of measurement
It will be measured according to the Cop Corn questionnaire

Intervention groups

1

Description
Intervention group:They will receive a diclofenac treatment (75 mg daily) one hour after meals daily. Furthermore, the herbal combination of licorice and ginger (capsules 500 mg) will be prescribed every 12 hours for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: They will receive a diclofenac treatment (75 mg daily) one hour after meals daily. Also, 500 mg of plasbo capsule will be prescribed every 12 hours for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital, Tehran, Iran
Full name of responsible person
Alireza Rahimnia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
30
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Alireza Rahimnia
Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Participants' data files, study protocol, statistical analysis map, statistical analysis, clinical study report and classification system will be shared. However, after making people unrecognizable, part of the data, such as information about the main consequence or the like, can be shared one hundred percent.
When the data will become available and for how long
The access period will start 6 months after publication
To whom data/document is available
Data will only be available to researchers working at academic and scientific institutions
Under which criteria data/document could be used
After publishing the data and the article, any kind of analysis is allowed by mentioning the source
From where data/document is obtainable
Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN.School of Pharmacy
What processes are involved for a request to access data/document
After the communication is established, the applicant must submit a written request to the relevant organization and the request will be answered within 4-5 months
Comments