

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 complete knee replacement based on VAS. 2- Comparison of the effect of licorice and ginger combination with diclofenac on inflammatory indicators (IL-6 and TNF- $\alpha$ ) 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)

##### Phone

+98 21 8821 1524

##### Email address

yunespanahi@bmsu.ac.ir

##### 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 placebo 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

#### Street address

Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN

#### City

Tehran

#### Province

Tehran

#### Postal code

1435916471

#### Phone

+98 21 8755 5131

#### Email

Dr.rahimnia@bmsu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Yunes Panahi

#### Street address

Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN.

#### City

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#### Province

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#### Phone

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#### Email

Yunespanahi@bmsu.ac.ir

### 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

Non-faculty physician

#### Latest degree

Specialist

#### Other areas of specialty/work

Orthopedics

#### Street address

Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN.

#### City

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#### Phone

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**Email**

dr.rahimnia@bmsu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Yunes Panahi

**Position**

Professor of Baqiyatallah University of Medical Sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Medical Pharmacy

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**Email**

yunespanahi@bmsu.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Alireza Rahmnia

**Position**

Non-faculty physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Phone**

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**Email**

dr.rahimnia@bmsu.ac.ir

**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**