Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Efficacy of "Squill Oxymel " in Treatment of Knee Osteoarthritis Compared with placebo.

Protocol summary

Summary

The aim of this study is to evaluate of therapeutic efficacy of traditional medicine product "Squill Oxymel" in patients with knee osteoarthritis . First, patients with osteoarthritis of the knee, according to the criteria approved by orthopedic specialist are recruited. Then the patients are informed about the project and presence of case and control groups and after obtaining the consent; they can be enrolled into the project. Then the selected patients based on clinical and radiological osteoarthritis ACR criteria are divided into the two treatment and placebo groups. The patients are randomized into the study groups and receive encoded drug (drug or placebo) to consume according to the instructions. Patient and physician have no information about the glass content(by double-blind randomized clinical trial). Considering the inclusion criteria and after filling the form and questionnaire by the patient, the patient will be given one week period as wash out of drug. X-rays of the knee is requested (if there is no x-ray in the past 6 months) along with the necessary tests to find patients with severe kidney or liver problems for exclusion criteria, such as BUN, CR, AST, ALT. Inflammatory tests, such as WBC, ESR, CRP and Specialized tests, such as IL6, SOD are measured as basic tests for patients. During this period, patients can use up to 4g / day of acetaminophen. The syrup will be used by dosage of two tablespoons every morning fasting with a glass of water for 2 months.The patients will be visited at weeks 0, 4 and 8 and at the end of the trial; the specialized tests(IL6, SOD) and inflammatory tests(WBC, ESR, CRP) are measured to compare the two groups. One month after the end of treatment, at week 12, clinical symptoms are reevaluated and the questionnaires and forms are filled again as the follow up to the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101124474N1**
Registration date: **2015-11-26, 1394/09/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-26, 1394/09/05

Registrant information

Name
Mojtaba Taheri
Name of organization / entity
College of Traditional Medicine, Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

1. Traditional Medicine and Materia Medica Research Center(TMRC), Shahid Beheshti University of Medical Sciences(Tehran - Iran) 2. Barij Essence Pharmaceutical Co(Kashan - Iran)

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of Efficacy of "Squill Oxymel " in Treatment of Knee Osteoarthritis Compared with placebo.

Public title
Effect of Squill Oxymel in Treatment of Knee Arthrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Age 40 to 80 years old that fill clinical and radiological criteria of ACR. after drug wash out,with VAS>40mm. clinical and radiological criteria of ACR: knee pain + osteophite in radiography + at least 1 of 3 below criteria: age up 50 years old; morning stiffness less than 30 minutes; crepitation of knee. Exclusion Criteria: history of rheumatoid arthritis and gout; history of knee surgery; patients with severe cardiovascular disease, including heart failure, advanced Class 3 and 4, sick sinus syndrome (SSS), 3rd degree atrioventricular block, Wolff Parkinson's White syndrome (WPW), ventricular tachycardia (VT), hypertrophic cardiomyopathy, aortic thoracic aneurysm; proven malignancies; GI bleeding(stomach bleeding); severe liver disease(esophageal varices and bleeding, encephalopathy, ascites); patients with Symptomatic gallstone(in history); severe renal disease(creatinine greater than 3mg / dl); joint injection of corticosteroids in the past three months; received oral corticosteroids in the past 4 weeks; oral or injectable NSAID in last seven days; received chondrotin sulfate or glucosamine, warfarin, clopidogrel, digitalis, capsaicin, quinidine, laxatives or any other drugs, according to pharmacologists opinion; pregnancy and Breast-feeding. Exit criteria during study: Not wanting to continue taking the drug by the patient for any reason; Allergy symptoms or complications to acetaminophen or squill oxymel; Any clinical condition that need to change a patient's treatment regimen.
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Shahid Beheshti University of Medical Sciences (IR.SBMU.REC
Street address
Office of Research Management, Shahid Beheshti University of Medical Sciences, side of Taleghani Hospital, Evin, Shahid Chamran Highway, Tehran
City
Tehran
Postal code
Approval date
2015-10-18, 1394/07/26
Ethics committee reference number
IR.SBMU.RAM.REC.1394.285

Health conditions studied

1

Description of health condition studied
knee osteoarthritis
ICD-10 code
M17
ICD-10 code description
Gonarthrosis

Primary outcomes

1

Description
pain
Timepoint
At the beginning of intervention and after 1 month, 2 months and 3 months after the beginning of intervention
Method of measurement
KOOS Pain and VAS

2

Description
Knee discomfort
Timepoint
At the beginning of intervention and after 1 month, 2 months and 3 months after the beginning of intervention
Method of measurement
KOOS Scoring

3

Description
Stiffness
Timepoint

At the beginning of intervention and after 1 month, 2 months and 3 months after the beginning of intervention

Method of measurement

KOOS Scoring

4

Description

Activites and daily living

Timepoint

At the beginning of intervention and after 1 month, 2 months and 3 months after the beginning of intervention

Method of measurement

KOOS Scoring

5

Description

Sport and recreation function

Timepoint

At the beginning of intervention and after 1 month, 2 months and 3 months after the beginning of intervention

Method of measurement

KOOS Scoring

6

Description

Quality of life

Timepoint

At the beginning of intervention and after 1 month, 2 months and 3 months after the beginning of intervention

Method of measurement

KOOS Scoring and SF26 WHO

Secondary outcomes

1

Description

SOD

Timepoint

At the beginning of intervention and 2 months later at the end of intervention

Method of measurement

Based on Lab data

2

Description

IL6

Timepoint

At the beginning of intervention and 2 months later at the end of intervention

Method of measurement

Based on Lab data

3

Description

CRP

Timepoint

At the beginning of intervention and 2 months later at the end of intervention

Method of measurement

Based on Lab data

4

Description

ESR

Timepoint

At the beginning of intervention and 2 months later at the end of intervention

Method of measurement

Based on Lab data

5

Description

WBC

Timepoint

At the beginning of intervention and 2 months later at the end of intervention

Method of measurement

Based on Lab data

Intervention groups

1

Description

Intervention group: Syrup of Squill Oxymel, 2 tablespoons in the morninig on empty stomach with a glass of lukewarm water for 8 weeks + Tablet of Acetaminophen up to 4 gr daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo Syrup made from brown sugar, 2 tablespoons in the morning on empty stomach with a glass of lukewarm water for 8 weeks + Tablet of Acetaminophen up to 4 gr daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shariat Panahi Clinic

Full name of responsible person

Mohammad Kazem Emami meybodi

Street address

No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Orthopedic Clinic of Bagheiyatallah Hospital

Full name of responsible person

Mojtaba Taheri

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Traditional Medicine College of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahmood Mosadegh

Street address

No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Traditional Medicine College of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

College of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mojtaba Taheri

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Associate Professor

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Person responsible for updating data

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College of Traditional Medicine, Shahid Beheshti University of Medical Sciences

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Position

Ph.D student ofTraditional Medicine

Other areas of specialty/work

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00

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty