Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 2521

Email address

taheri.dr@sbmu.ac.ir

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
Street address
City
Tehran

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

Contact
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Full name of responsible person
Roshanak Mokaberinegad
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Associate Professor
Other areas of specialty/work
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Person responsible for updating data

Contact
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College of Traditional Medicine, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mojtaba Taheri
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Ph.D student ofTraditional Medicine
Other areas of specialty/work
Street address
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran
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00
Fax
Email
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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