Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Satureja Hortensis L .Leaf Powder on Pain and Pro inflammatory Cytokines (TNF-α , IL-1β) in Patients with Knee Osteoarthritis

Protocol summary

Summary

The aim of this study is to evaluate the influence of leaf powder savory pain and pro-inflammatory cytokines in patients with osteoarthritis of the knee. This study is a double-blind, placebo-controlled study in phase I clinical trials. The study population of patients with knee osteoarthritis are 40 to 70 years. The main inclusion criteria included individuals between the ages of 40 to 70 years; Knee osteoarthritis is diagnosed according to American College of Rheumatology.The main exclusion criteria included: patients less than 80% capsules are consumed; Patients who have inflammatory diseases, metabolic (diabetes), cancer, liver and kidney failure. Intervention in this study is daily consumption of 3 capsules dried savory leaves or 3 placebo capsules. Intervening period is between 23/09/2013 to 03/03/2014. In this study Pain, IL 1 beta and TNF-alpha will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112515542N1**
Registration date: **2013-12-17, 1392/09/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-17, 1392/09/26

Registrant information

Name

Maryam Asadi

Name of organization / entity

Ahvaz jundi shapoor university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-03-03, 1392/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Satureja Hortensis L .Leaf Powder on Pain and Pro inflammatory Cytokines (TNF-α , IL-1β) in Patients with Knee Osteoarthritis

Public title

The Effect of Satureja Hortensis L. on Knee Osteoarthritis Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

The main inclusion criteria included individuals between the ages of 40 to 70 years; Knee osteoarthritis is diagnosed according to American College of Rheumatology. The main exclusion criteria included: patients less than 80% capsules are consumed; Patients who have inflammatory diseases, metabolic (diabetes),

cancer, liver and kidney failure.

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

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

Yazd University of Medical Sciences

Street address

Imam Reza Researh and Educational Complex , Daneshju Blvd.

City

Yazd

Postal code

8916189165

Approval date

2013-06-10, 1392/03/20

Ethics committee reference number

17/1/48454/پ

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

pain

Timepoint

Measured at baseline and 2 months after studies

Method of measurement

Visual Analogue linear scale

2

Description

TNF alpha

Timepoint

Measured at baseline and 2 months after studies

Method of measurement

ELISA

3

Description

IL1 beta

Timepoint

Measured at baseline and 2 months after studies

Method of measurement

ELISA

Secondary outcomes

1

Description

Heartburn

Timepoint

Every two weeks

Method of measurement

Question of patients

2

Description

Feeling the heat

Timepoint

Every two weeks

Method of measurement

Question of patients

Intervention groups

1

Description

Daily consumption of three capsules of 200 mg dried savory leaves half an hour after meals for 2 months.

Category

Treatment - Drugs

2

Description

Daily consumption of three capsules of 200 mg powder of starch half an hour after meals for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam o Alanbia Subspecialty Clinic

Full name of responsible person
Ali Dehghan Assistant Professor of Rheumatology

Street address
Central Building of Yazd University of Medical Science, Shahid Bahonar Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Hasan Mozaffari Khosravi

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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
Yazd 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

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Masters student in Nutrition and Health Sciences

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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