Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

efficacy of Saussurea costus (Qost) oil, Iranian Traditional Medicine product, on female urinary incontinence; double blinded randomized clinical trial

Protocol summary

Summary

Objectives: evaluating the efficacy of Saussurea costus oil, an Iranian traditional medicine product, on signs and symptoms and quality of life of female urinary incontinence according to International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) and Incontinence Quality of Life (I-QOL) questionnaires compared to placebo Design, Setting and conduct: double blinded (Information on the type of drug and the patient in a sealed envelope is presented to a third party so that both the patient and the researchers are unaware of the type of oil).In this randomized clinical trial, randomized blocking method has been done. 30-70 old women with stress or mixed urinary incontinence are allocated into placebo and intervention groups. Each group having 40 subjects.It is two center (pelvic floor clinic in Imam Khomeini Hospital of Tehran University of Medical Sciences and Traditional medicine center in Ardabil). Inclusion criteria: 30-70 old women with stress or mixed urinary incontinence who have been symptomatic for at least 3 months Exclusion criteria: acute or recurrent urine infection Interventions: Intervention group will receive Saussurea Costus oil while the other group receives placebo oil. Drug used in both groups is Local application twice a day applied to area between the navel and pubic region. Results will be evaluated on weeks 3 and 6 and one month after the end of intervention. Evaluation of possible skin side effects will be done on weeks 3 and 6 of the study. Major outcome variations: evaluating symptoms severity and quality of life after treatment using ICIQ-SF and I-QOL questionnaires that validated in Persian

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110924970N1**
Registration date: **2016-01-15, 1394/10/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-15, 1394/10/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tehran University of Medical Sciences, University School of Traditional Medicine

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-09-19, 1395/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
efficacy of Saussurea costus (Qost) oil, Iranian Traditional Medicine product, on female urinary incontinence; double blinded randomized clinical trial

Public title
efficacy of Saussurea costus (Qost) oil on female urinary incontinence

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 30-70 old women with stress or mixed urinary incontinence; Being symptomatic for at least 3 months; not been treated for at least 2 week before study; Who are willing to participate in research and Have signed a consent form; After explaining the research objectives of the study and informed consent, patients will be enrolled. Exclusion criteria: acute or recurrent urinary tract infection; pregnancy or lack of contraception; allergy to oily drug products; chronic degenerative neuromuscular disease; Bladder cancer or previous record of it; pain of bladder or painful urine voiding; disease or drugs that were be effective on our research results such as diuretics; record of pelvic surgery during past one year; drug misuse during study; Unwillingness to continue participation in the study; drug side effects during study

Age
From **30 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization is performed using randomized blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
501, 5th Floor, Central Building of Tehran University of Medical Sciences, Keshavarz and Qods Junction, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-11-07, 1394/08/16

Ethics committee reference number
IR.TUMS.REC.1394.1113

Health conditions studied

1

Description of health condition studied
Stress urinary incontinence

ICD-10 code
N39.3

ICD-10 code description
Stress incontinence

2

Description of health condition studied
Mixed urinary incontinence

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
Frequency of urinary leakage

Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

2

Description
The amount of urine leakage

Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

3

Description
Time leakage: leakage befor sleep

Timepoint
At the beginning of the intervention, after 3 and 6 weeks,

1 month after end of intervention

Method of measurement

International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

4

Description

Time of leakage: leakage before reaching the bathroom

Timepoint

At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement

International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

5

Description

Time leakage: leakage of urine with coughing and sneezing

Timepoint

At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement

International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

6

Description

The leakage of urine: leakage of urine with exercise

Timepoint

At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement

International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

7

Description

The leakage of urine: urine leakage after urination immediately prior to wearing underwear

Timepoint

At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement

International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

8

Description

Assessment of changes in quality of life

Timepoint

At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement

Incontinence Quality of Life (I-QOL) questionnaire

Secondary outcomes

1

Description

presumptive skin complications

Timepoint

3 weeks after research start and 6 weeks after that (end of intervention)

Method of measurement

Measurement form of drug complications According to Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0

Intervention groups

1

Description

Intervention group: Saussurea costus oil; local use; frequency of use of the drug twice a day; Area of oil application is navel to pubic area; Each time the oil volume is 2/3 ml; Intervention time is 6 weeks

Category

Treatment - Drugs

2

Description

control group: placebo oil; local use; local use; Frequency of use of the drug twice a day; Area of oil application is navel to pubic area; Each time the volume of oil is 2/3 ml; Intervention time is 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pelvic Floor Clinic of Imam Khomeini Hospital belongs to Tehran University of Medical Sciences

Full name of responsible person

Zahra Niktabe

Street address

Keshavarz Blvd, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, School of Traditional medicine, Tehran University of Medical Sciences

Full name of responsible person

Roja Rahimi

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School of Traditional medicine, Tehran University of Medical Sciences, Giti Alley, Vafamanesh Street, Heravi Square, Pasdaran Street, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, School of Traditional medicine, Tehran 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

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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