Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation on effect of mixed herbal medicines (fennel,chamomile,saffron)on menopausal syndrome and hormonal changing and quality of life in menopausal women in Mashhad with 4 groups in different doses and placebo controlled

Protocol summary

Summary

objective: The aims of this study are the Investigation effect of mixed herbal medicines on menopausal syndrome , quality of life and hormones changes. Design & Setting and conduct: a triple blind randomized clinical trial study and placebo controlled trial conducted on 120 menopausal women for 12 weeks in Mashhad. The participants randomly allocated based on age, in four groups.Group Placebo (C),group A (250 mg chamomile+30 mg fennel+15 mg saffron), group B (100 mg chamomile+120 mg fennel+60 mg saffron) and group D (500 mg chamomile+600 mg fennel+30 mg saffron). All participants take 25 drops of mixed herbal medicines extracts daily. Intervention: all participants completed demographic, MRS questioner, quality of life questioner at the beginning, at the 6th week and at the end of trial .Then one group take placebo, the other group take low-dose of extract, third group take medium-dose of extract and last group take high dose of the extract daily for 12 weeks. Also laboratory tests (estrogen, progesterone, Testosterone and LH, FSH)are done at the first and at the end of the intervention. Main Outcome measures: Menopause symptoms ,Quality of life and hormones changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092429950N1**
Registration date: **2017-05-29, 1396/03/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

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Mitra Mahdavian
Name of organization / entity
Mashhad university of medical science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical science

Expected recruitment start date

2016-04-29, 1395/02/10

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on effect of mixed herbal medicines (fennel,chamomile,saffron)on menopausal syndrome and hormonal changing and quality of life in menopausal women in Mashhad with 4 groups in different doses and placebo controlled

Public title

Investigation on effect of mixed herbal medicines (fennel,chamomile,saffron) on menopausal syndrome,hormonal changing and quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: lack of menstruation in last 12 months; having tested showed the evidence of menopause; having menopausal syndrome; the range of the age is between 45 - 65 years. Exclusion criteria : using anti-anxiety drugs; using antidepressants; using hormones such as: estrogen and progesterone in the last 6 months; using anticoagulant and NSAIDs such as: ibuprofen; having asthma and allergies; thyroid diseases; psychosomatic disorders; pheochromocytoma; carcinoma; leukemia; cancer; lack of proper use of herbal medicines in this study; creating skin irritation and allergy drug.

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical science

Street address

Central department NO1, 18 th Daneshgah , Daneshgah Ave,Mashhad

City

Mashhad

Postal code

9138813944

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC..1394.499

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N 95.1

ICD-10 code description

is a billable/specific ICD-10-CM code that can be used to indicate a diagnosis for reimbursement purposes. This is the American ICD-10-CM version of N95.1. Other international versions of ICD-10 N95.1 may differ.

Primary outcomes

1

Description

Menopausal syndrome

Timepoint

At the beginning of the study,6 weeks later and 12 weeks later at the end of intervention

Method of measurement

Menopause Rating Scale (MRS)

2

Description

Quality of life

Timepoint

At the beginning of the study,6 weeks later and 12 weeks later at the end of intervention

Method of measurement

Quality of life questioner(QOL)

3

Description

Hormones changes

Timepoint

At the beginning of the study and 12 weeks later at the end of intervention

Method of measurement

Laboratory measurements

Secondary outcomes

1

Description

Depression

Timepoint

at the beginning,6 weeks later and 12 weeks later at the end of intervention

Method of measurement

Beck questioner

2

Description
Insomnia
Timepoint
at the beginning,6 weeks later and 12 weeks later at the end of intervention
Method of measurement
ISI questioner

Intervention groups

1

Description
Group 1 low dose: 250 mg chamomile+30 mg fennel+15 mg saffron ,25 drops daily
Category
Treatment - Drugs

2

Description
Group 2 high dose: 1000 mg chamomile+120 mg fennel+60 mg saffron,25 drops daily
Category
Treatment - Drugs

3

Description
Group 3 placebo:sterile dH2O,25 drops daily
Category
Treatment - Drugs

4

Description
Group 4 intermediate dose : 500 mg chamomile+60 mg fennel+30 mg saffron,25 drops daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
All over the city ,Mosque,Religious ceremony
Full name of responsible person
because of lack participant in treatment centers we decided take the sample in all over the city wit
Street address
Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Mashhad university of medical science
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Central department No 1,18th Daneshgah, Daneshgah Ave
City
Mashhad
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 and Technology of Mashhad university of medical science
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
Mashhad university of medical science
Full name of responsible person
Dr. Khadije Mirzaii
Position
P.h.D in Reproductive health/academic staff
Other areas of specialty/work
Street address
Daneshgah Ave.university of Nursing &Midwifery
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Phone
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Email
mirzaiikh@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing &Midwifery
Full name of responsible person

Dr khadije Mirzaii

Position

P.h.D in Reproductive health/academic staff

Other areas of specialty/work

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Person responsible for updating data

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Mitra Mahdavian

Position

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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