Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the effectiveness of Vitagnos, Gabapentin and Paroxetine on the early complications of menopause in women: a double-blind clinical trial.

Protocol summary

Study aim
Comparison of the effectiveness of Vitagnos, Gabapentin and Paroxetine on the early complications of menopause in women

Design
Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 90 patients used the Excel software rand function for randomization.

Settings and conduct
This project was carried out at Shahid Sadoughi Hospital in Yazd. Patients in three groups of 30 people for 8 weeks use 2 Vitagnos tablets or 1 Paroxetine tablet or Gabapentin capsule daily.

Participants/Inclusion and exclusion criteria
Patients who have been amenorrhoeic for at least one year and have hot flashes 3 or more times in 24 hours. They do not have an uncontrolled underlying disease and do not use drugs containing estrogenic or pseudo-estrogen compounds.

Intervention groups
In order to evaluate the effectiveness of Vitagenus in the complications of early menopause, a group of 30 people is given Vitagenus, a group of 30 people is given paroxetine and a group of 30 people is given gabapentin.

Main outcome variables
Severity of hot flashes, The frequency of hot flashes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181208041882N16**
Registration date: **2023-10-28, 1402/08/06**
Registration timing: **retrospective**

Last update: **2023-10-28, 1402/08/06**
Update count: **0**

Registration date
2023-10-28, 1402/08/06

Registrant information
Name
behrooz heydari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3820 8699
Email address
b.heydari@ssu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2023-06-21, 1402/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Vitagnos, Gabapentin and Paroxetine on the early complications of menopause in women: a double-blind clinical trial.

Public title
The effectiveness of Vitagnos, Gabapentin and Paroxetine on early menopause complications
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 45 to 60 years Amenorrhea for at least 12 months At least 3 hot flushes in 24 hours

Exclusion criteria:

Women with abnormal menopause Patients with chronic diseases (thyroid disease, psychosomatic disease, pheochromocytoma, carcinoid, leukemia, cancer and other known systemic diseases such as hypertension, diabetes, heart diseases) Consumption of hormones and supplements (containing estrogen-like compounds such as soy)

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Patients were randomly assigned to two groups by using Excel software rand function.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients, the clinical caregiver and the outcome assessor were not aware of the type of medication the patients received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2017-11-29, 1396/09/08

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.209

Health conditions studied

1

Description of health condition studied

early complications of menopause

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Menopause symptoms

Timepoint

Week 0, 4 and 8

Method of measurement

based on Kupperman Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients suffering from early complications of menopause use gabapentin 100 mg orally daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Patients suffering from early complications of menopause use vitagnos orally twice a day for 8 weeks.

Category

Treatment - Drugs

3

Description

Control group: Patients suffering from early complications of menopause use paroxetine 20 mg orally daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi hospital
Full name of responsible person
Mojgan Karimi Zarchi
Street address
Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh, Yazd.
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۸۸۷۸۵۷
Phone
+98 35 3822 4000
Fax
Email
sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abarghouei
Street address
Shahid Sadoughi University of medical sciences, Shohadaye Gomnan Blvd, Alem Sq
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3146 2150
Email
abargouei@ssu.ac.ir

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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Behrooz Heydari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd, Alem Sq
City
Yazd
Province
Yazd
Postal code
8915173143
Phone
+98 35 3820 3410
Email
b.heydari@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Behrooz Heydari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Sadoughi University of medical sciences, Shohadaye Gomnan Blvd, Alem Sq
City
Yazd
Province
Yazd
Postal code
8915173143
Phone
+98 35 3820 3410
Email
b.heydari@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Behrooz Heydari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Shahid Sadoughi University of medical sciences, Shohadaye Gomnam Blvd, Alem Sq

City
Yazd

Province
Yazd

Postal code
8915173143

Phone
+98 35 3820 3410

Email
b.heydari@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After nonrecognition, all data can be share

When the data will become available and for how long
6 months after publication

To whom data/document is available
All of researchers

Under which criteria data/document could be used
Nothing

From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir

What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.

Comments