Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effectiveness of Gabapentin vaginal gel on pain control in patients with Dyspareunia; A double-blind randomized clinical trial

Protocol summary

Study aim
Determining the effectiveness of Gabapentin vaginal gel on patients with Dyspareunia

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 60 patients, using dice and sealed envelopes for randomization.

Settings and conduct
Shahid Sadoughi Hospital, Women's Clinic, Yazd, patients who meet the inclusion criteria are placed in one of the two treatment groups with Gabapentin gel product (group A) or Basic Hydrogel (group B). Randomization is done based on the (RAND) function of Excel, and based on this, a table of random numbers is prepared, and the patients are placed in group A or B according to the rows of this table, and receive the product related to their group. All of the creams of one numbered form will be available to the attending physician and them. Patients will be evaluated for one month on days 0, 7, 14, 21 and 28

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 50 years, married, suffering from dyspareunia, not allergic to gabapentin and vaginal gel base ingredients, not taking vaginal painkillers or gabapentin within a week before the start of the study, Consent to participate in the study and complete the informed consent form. non-entry criteria: history of psychiatric diseases (psychosis), acute and chronic vaginal infection, female genital cancer, pregnancy, and breastfeeding.

Intervention groups
intervention group: Treatment with Gabapentin vaginal gel (gabapentin, carbomer, hydroxypropyl methylcellulose) 5%, once a day, topical use (vaginally) for up to 4 weeks control group: Treatment with placebo vaginal gel (carbomer, hydroxypropyl methylcellulose), once a day, topical application (vaginally) for up to 4 weeks

Main outcome variables
NRS pain scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191106045356N13**
Registration date: **2022-10-31, 1401/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-31, 1401/08/09**
Update count: **0**

Registration date
2022-10-31, 1401/08/09

Registrant information

Name
Mohsen Zabihi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 3865

Email address
mzabihi100@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of Gabapentin vaginal gel on pain control in patients with Dyspareunia; A double-blind randomized clinical trial

Public title
Evaluation of the effects of Gabapentin vaginal gel on Dyspareunia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
married Suffering from Dyspareunia Insensitivity to gabapentin and vaginal gel base ingredients Not taking vaginal painkillers or systemic gabapentin one week before the start of the study Consent to participate in the study and complete the informed consent form

Exclusion criteria:
History of psychiatric diseases Acute and chronic vaginal infection cancer of the female genital tract Pregnancy and breastfeeding

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Randomization will be done based on the (RAND) function of Excel and based on this, a table of random numbers is prepared, and the patients are placed in groups A or B according to the rows of this table, and receive the product related to their group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be done in a double-blind manner. Patients and doctors (therapist and evaluator) will not know about the intervention. Worms are numbered by one of the researchers who does not intervene in the study process (treatment, evaluation and data analysis) with labels one and two, and only the same researcher knows about the numbering of worms. Then the numbered creams are delivered to the patients by the doctor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
thics committee of ٔShahid Sadoughi University of Medical Sciences

Street address
Alem sq.

City
Yazd

Province
Yazd

Postal code
۸۹۱۶۹۷۸۴۷۷

Approval date
2022-06-26, 1401/04/05

Ethics committee reference number
IR.SSU.MEDICINE.REC.1401.073

Health conditions studied

1

Description of health condition studied
Dyspareunia

ICD-10 code
N94.1

ICD-10 code description
Dyspareunia

Primary outcomes

1

Description
NSR Pain Scale

Timepoint
Measurement of NRS scale at the beginning of the study and on days 7, 14, 21 and 28 days after the start of gabapentin gel consumption.

Method of measurement
NRS Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 patients with dyspareunia who were treated with 5% gabapentin vaginal gel (gabapentin, hydroxypropyl methylcellulose and carbomer), topical use (vaginal), daily for one to one

month.

Category

Treatment - Drugs

2

Description

Control group: 30 patients with dyspareunia who were treated with placebo vaginal gel (hydroxypropyl methyl cellulose and carbomer) used topically (vaginally), once a day for a month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital

Full name of responsible person
Dr Leyla Zanbagh

Street address
Shahid Sadoughi Hospital, Ibn Sina Blvd, Yazd

City
Yazd

Province
Yazd

Postal code
8916978477

Phone
+98 35 3822 4000

Email
mzabihi100@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Mohsen Zabihi

Street address
Shahid Sadoughi University, Prof. Hessabi Ave, Yazd.

City
Yazd

Province
Yazd

Postal code
8916978477

Phone
+98 35 3822 4000

Email
mzabihi100@gmail.com

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
Mohsen Zabihi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Alem sq.

City
Yazd

Province
Yazd

Postal code
8916774520

Phone
+98 35 3820 3865

Fax

Email
mzabihi100@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Mohsen Zabihi

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Professor

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mzabihi100@gmail.com

Person responsible for updating data

Contact

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Yazd University of Medical Sciences

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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

There is no further information

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

Mohsen Zabihi Professor of Pharmacology, Yazd University of Medical Sciences +98 913 153 6813 mzabihi100@gmail.com

What processes are involved for a request to access data/document

No specific details are considered

Comments