Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vaginal oxytocin on sexual function in lactating women: a randomised controlled trial

Protocol summary

Study aim
To determine the effect of vaginal oxytocin on sexual dysfunction in lactating women
Design
Clinical trial, with control group, with parallel groups, triple blind, randomized
Settings and conduct
This study will be conducted on 68 lactating women referring to community health centers in Tabriz. Participants will be divided into two groups by randomized blocking method and an assignment ratio of 1:1. The intervention group will receive Oxytocin jel and the control group will receive placebo jel. Both groups will take drug or placebo once a day for 8 weeks.
Participants/Inclusion and exclusion criteria
The participants will be lactating women during 6 weeks and 6 months after delivery who obtain female Sexual Function Index (FSFI) score lower than 26.5 and a depression score of less than 13 based on the Edinburg depression scale at the initial evaluation.
Intervention groups
the intervention group will receive oxytocin jel and the control group will receive placebo jel
Main outcome variables
The main outcome variable include sexual function that will be assessed by female sexual function index before and eight weeks after intervention.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120718010324N55**
Registration date: **2020-05-27, 1399/03/07**
Registration timing: **prospective**

Last update: **2020-05-27, 1399/03/07**
Update count: **0**
Registration date
2020-05-27, 1399/03/07

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-29, 1399/03/09
Expected recruitment end date
2020-09-20, 1399/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vaginal oxytocin on sexual function in lactating women: a randomised controlled trial

Public title
The effect of vaginal oxytocin on sexual function in lactating women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Lactating women Passing at least 6 weeks and 6 months after delivery Female Sexual Function Index (FSFI) score less than 26.5 at the initial evaluation Having a depression score of less than 13 based on the Edinburg Postpartum Depression Scale Having active life based on sexual relationship

Exclusion criteria:

Pregnant women A history of grief and postpartum depression A history of taking depression and other psychiatric drugs History of hormone therapy for sexual dysfunction during the past two weeks A history of chemotherapy or pelvic radiation therapy Any chronic and uncontrolled illness such as diabetes

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4 and 6 and the allocation ratio of 1:1. A person not involved in the sampling will generate allocation sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2020-05-14, 1399/02/25

Ethics committee reference number

IR.TBZMED.REC.1399.121

Health conditions studied

1

Description of health condition studied

Sexual dysfunctionse

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Sexual function

Timepoint

Before and 8 weeks after intervention

Method of measurement

Female Sexual Function Index

Secondary outcomes

1

Description

Sexual satisfaction

Timepoint

Before and 8 weeks after intervention

Method of measurement

Sexual Satisfaction Scale for Women

2

Description

Depression

Timepoint

Before and 8 weeks after intervention

Method of measurement

Edinbuurgh Postnatal Depression Scale

Intervention groups

1

Description
The intervention group will receive oxytocin vaginal jel daily for 8 weeks.
Category
Treatment - Drugs

2

Description
The control group will receive placebo vaginal jel daily for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Community health centers of Tabriz
Full name of responsible person
Arezu Mesbahi
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Sponsors / Funding sources

1

Sponsor
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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
Tabriz 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participants data is confidential.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of clinical study will be published as article.
When the data will become available and for how long
Immediately after publishing the results.
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific using with citation to article
From where data/document is obtainable
Email: mirghafourvandm@tbzmed.ac.ir
What processes are involved for a request to access data/document
Up to one week after communication by email
Comments