

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

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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

Edinburgh 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

Street address

Nursing and Midwifery faculty, South Shariati street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

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

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iro@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

Full name of responsible person

Arezu Mesbahi

Position

MSc student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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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: mirghaforvandm@tbzmed.ac.ir

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

Up to one week after communication by email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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