

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of using vaginal estrogen cream versus not using on endometrial thickness in infertile women under embryonal transfer: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of using vaginal estrogen cream versus not using on endometrial thickness in infertile women under embryonal transfer Design: A randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 20 to 35 years; infertility. Exclusion criteria: Estradiol contraindication; uterus problem. Intervention group: Conjugate vaginal estrogen cream once a day for 11 days plus estradiol tablet 6 mg once a day for 11 days Control group: Estradiol tablet 6 mg once a day for 11 days. Primary outcome: Measuring the endometrial thickness using sonography before intervention and on 5 and 9 and 11 days of the menstrual cycle. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The examiner will not be aware of the type of treatment, therefore the study will be run as a single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708309014N180**

Registration date: **2017-09-03, 1396/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-03, 1396/06/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using vaginal estrogen cream versus not using on endometrial thickness in infertile women under embryonal transfer: a single blind randomized clinical trial

Public title

Effect of using vaginal estrogen cream versus not using on endometrial thickness in infertile women under embryonal transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 20 to 35 years; infertility.
 Exclusion criteria: Estradiol contraindication; uterus problem.

Age
 From **20 years** old to **35 years** old

Gender
 Female

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **100**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The examiner will not be aware of the type of treatment, therefore the study will be run as a single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
 Hamadan University of Medical Sciences, Shahid
 Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-08-06, 1395/05/16

Ethics committee reference number

IR.UMSHA.REC.1395.251

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Measuring the endometrial thickness

Timepoint

before intervention and on 5 and 9 and 11 days of the menstrual cycle

Method of measurement

using sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Conjugate vaginal estrogen cream once a day for 11 days plus estradiol tablet 6 mg once a day for 11 days

Category

Treatment - Drugs

2

Description

Control group: Estradiol tablet 6 mg once a day for 11 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nazanin Sahebi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
 Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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, Hamadan
University of Medical Sciences

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**

Fatemieh Hospital

Full name of responsible person

Nazanin Sahebi

Position

Medical Student

Other areas of specialty/work**Street address**

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

nazaninsahebi@yahoo.com

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Fatemieh Hospital

Full name of responsible person

Nazanin Sahebi

Position

Medical Student

Other areas of specialty/work**Street address**

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

nazaninsahebi@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code**Phone**

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

Web page address**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