

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of Clindamycin suppository and Lactobacilli suppository in vaginal microbiome on in-vitro fertilization (IVF) in patients candidate for embryo transfer referring to Omid clinic, Hamedan: single blind randomized clinical trial

Protocol summary

Registration date: **2021-01-06, 1399/10/17**
Registration timing: **registered_while_recruiting**

Study aim

To compare following variables in different study arms: number of embryos and oocytes, quality of embryo, age of parents, uterous anomaly, method of embryo transfer, traumatization, ET difficulty, fertilization rate, implantation rate, preterm labor, PROM, early abortion with FHR, early abortion without FHR, chemical pregnancy, life birth rate in different study arms (clindamycin suppository-lactobacilli suppository-placebo)

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

roghayeh anvari aliabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 8080

Email address

anvar_anvari@yahoo.com

Design

Clinical trial with placebo group, with parallel groups, single-blinded, randomized with permuted block randomization with sample size of 108 patients

Recruitment status

Recruitment complete

Funding source

Settings and conduct

All patients candidate for IVF referring to Omid clinic, Hamedan, Iran are enrolled in this study. Patients who are enrolled in the study will receive treatment by a care provider who is blinded to the type of drugs.

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2023-03-21, 1402/01/01

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients candidate for IVF referring to Omid clinic, Hamedan, Iran. Exclusion criteria included poor responder patients and those with severe male infertility

Actual recruitment start date

empty

Actual recruitment end date

empty

Intervention groups

Clindamycin suppository, Lactobacilli suppository, Placebo

Trial completion date

empty

Main outcome variables

Implantaion rate, PROM, Abortion, Life birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200819048456N1**

Scientific title

Comparison of the effect of Clindamycin suppository and Lactobacilli suppository in vaginal microbiome on in-vitro fertilization (IVF) in patients candidate for embryo

transfer referring to Omid clinic, Hamedan: single blind randomized clinical trial

Public title

The effect of Clindamycin and Lactobacilli suppository on in-vitro fertilization (IVF) results

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for IVF referring to Omid clinic, Hamedan, Iran

Exclusion criteria:

Poor responder Severe male infertility

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Care provider

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

we used permuted block randomization in this study. patients were randomly assigned to 3 blocks (each containing 6 persons).

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients who are clinically asymptomatic will be enrolled in the study and receive treatment by a care provider who is blinded to the type of drugs

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Fatemieh hospital, Pasdaran street

City

Hamedan

Province

Hamadan

Postal code

6517789971

Approval date

2020-10-25, 1399/08/04

Ethics committee reference number

IR.UMSHA.REC.1399.613

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Implantation rate

Timepoint

2 weeks

Method of measurement

Sonography

Secondary outcomes

1

Description

Prelabor rupture of membranes

Timepoint

22 to 37 weeks

Method of measurement

Yes/ no questionnaire

2

Description

Life birth rate

Timepoint

38 weeks

Method of measurement

Yes/ no questionnaire

3

Description

Abortion rate

Timepoint

12 weeks

Method of measurement

Yes/ no questionnaire

Intervention groups

1

Description

Intervention group: clindamycin suppository

Category

Treatment - Drugs

2

Description

Intervention group: lactobacilli suppository

Category

Treatment - Drugs

3

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid clinic, Hamedan

Full name of responsible person

Roghayeh Anvari Aliabad

Street address

Fatemieh hospital, Pasdaran street

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Postal code

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Email

anvar_anvari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Fahmideh street, Hamedan

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Hamedan

Province

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6517838678

Phone

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Pub@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Roghayeh Anvari aliabad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Roghayeh Anvari aliabad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

data for the method of RCT and primary outcome will be published

When the data will become available and for how long

6 months after publish of results

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

after sending the research proposal, data will be available

From where data/document is obtainable

via email : anvar_anvari@yahoo.com

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

access to the data will be available as soon as possible after reading the research proposal

Comments

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Roghayeh Anvari aliabad

Position

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Latest degree

Specialist

Other areas of specialty/work

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