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

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)

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

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.

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

Intervention groups
Clindamycin suppository, Lactobacilli suppository, Placebo

Main outcome variables
Implantaion rate, PROM, Abortion, Life birth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200819048456N1**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **registered_while_recruiting**

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

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

City

Hamedan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3834 0266

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

City

Hamedan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3838 0924

Email

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

Street address

Pasdaran square, Fatemiyeh hospital

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 8080

Fax

Email

anvar_anvari@yahoo.com

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

Gynecology and Obstetrics

Street address

Pasdaran square, Fatemiyeh hospital

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 8080

Fax

Email

anvar_anvari@yahoo.com

Person responsible for updating data

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

Street address

Pasdaran square, Fatemiyeh hospital

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 8080

Fax

Email

anvar_anvari@yahoo.com

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