

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of pregnancy rate in artificial and stimulation cycles with natural cycle in women candidate vitrified

Protocol summary

Summary

The aim of this study is to compare pregnancy rates of exogenous protocols and ovarian stimulation Protocols with natural protocol in women undergoing receiving blastocyst embryo freezing. In this randomized clinical trial, 150 patient with inclusion criteria (all healthy women 18 to 40 years, etc.) And exclusion criteria (sever Endometriosis, etc.) are selected. No drug is given for the control group (natural). While follicles reach to 18-20 mm, shape and thickness of the endometrium are noted. After 36-38 hours ovulation is confirmed by vaginal ultrasound and in 4 days blastocyst is transferred. In the first intervention experimental group (Stimulation), patients are taken Clomiphene Citrate tablets 100 mg daily from the fifth day to the ninth day of the cycle. While follicles reach to 18-20 mm, shape and thickness of the endometrium are noted. After 36-38 hours ovulation is confirmed by vaginal ultrasound, and blastocyst is transferred in 4 days. In the second intervention experimental group (Artificial), from the third day of the cycle, Estradiol vale rate tablets 6 mg is given per day. When the endometrial thickness is greater than 8 mm, the shape and thickness of the endometrium is noted. From this special day, 100 mg injection of progesterone along with Estradiol is given daily. Five days after starting progesterone, blastocyst is transferred. If the endometrial thickness doesn't get more than 8 mm in 15th day, Estradiol dose will be increased to 8 mg. In this method, the progesterone as a support would be continued till clarifying the pregnancy test in consistency with getting positive of pregnancy test until sixth week to eighth week of pregnancy. At the end, the primary outcome, number of pregnancies and abortions done in the artificial and stimulation protocols with natural protocol in women undergoing freeze blastocyst transfer are compared. Hence, secondary outcome, endometrial thickness and shape in two protocols Stimulation and artificial with natural protocol are compared as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408021760N36**

Registration date: **2014-09-17, 1393/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregnancy rate in artificial and stimulation cycles with natural cycle in women candidate vitrified

Public title

Comparison of pregnancy rate in artificial and stimulation cycles with natural cycle in women candidate vitrified

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All healthy women 18 to 40 years with a BMI = 20-32 Exclusion criteria: Women with PCOs; untreated thyroid disorders; Severe Endometriosis; Patients with one ovarian or uterine and ovarian pathology; FSH more than 15 IU / LI on day 3 of the cycle; Poor Response; Smokers; Abnormalities of the uterus; Patients with diet changes and medication from 2 months ago; Professional Athletes

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Babol University of Medical sciences

Street address

Ganjafroz Avenue, Babol University of Medical sciences

City

Babol

Postal code**Approval date**

2014-06-09, 1393/03/19

Ethics committee reference number

4232/30/پ/ز

Health conditions studied**1****Description of health condition studied**

In vitro fertilization

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes**1****Description**

Pregnancy

Timepoint

Sixth week until the eighth week after embryo transfer

Method of measurement

SONO - Vaginal

2**Description**

The number of abortions performed

Timepoint

After 10 weeks of gestational sac formation

Method of measurement

clinical

Secondary outcomes**1****Description**

Form Endometrium

Timepoint

Day of HCG injection

Method of measurement

SONO - Vaginal

Intervention groups**1****Description**

Intervention Group 2: In the second intervention experimental group (Artificial), from the third day of the cycle, Estradiol vale-rate tablets 6 mg is given per day. When the endometrial thickness is greater than 8 mm, the shape and thickness of the endometrium is noted. From this special day, 100 mg injection of progesterone along with Estradiol is given daily. Five days after starting progesterone, blastocyst is transferred. If the endometrial thickness doesn't get to more than 8 mm in 15th day, Estradiol dose will be increased to 8 mg. In this

method, the progesterone as a support would be continued till clarifying the pregnancy test in consistency with getting positive of pregnancy test until sixth week to eighth one of pregnancy

Category

Treatment - Drugs

2

Description

Intervention Group 1: In the first intervention experimental group (Stimulation), patients are taken Clomiphene Citrate tablets 100 mg daily from the fifth day to the ninth day of the cycle. While follicles reach to 18-20 mm, shape and thickness of the endometrium are noted. After 36-38 hours, ovulation is confirmed by vaginal ultrasound, and blastocyst is transferred in 4 days.

Category

Treatment - Drugs

3

Description

Control Group: No drug is given for the control group (natural). While follicles reach to 18-20 mm, shape and thickness of the endometrium are noted. After 36-38 hours, ovulation is confirmed by vaginal ultrasound and in 4 days blastocyst is transferred.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & infertility hospital

Full name of responsible person

Dr. Otoufeh Sheikhi

Street address

Fatemeh-zahra Infertility and Reproductive Health Research Center, Old Road, Amol- Babol, After Mohammad Hassan Khan Bridge

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Babol University of Medical sciences, Ganjafroz Avenue

City

Babol

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, Babol 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

Fatemehzahra Infertility & reproductive Health Reseach Center

Full name of responsible person

Fr. Otoufeh Sheikhi

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work
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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