

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison The Effect of Minimal stimulation and double stimulation protocol in poor ovarian response in ICSI cycle

Protocol summary

Study aim

Comparison of ovulation induction results with double stimulation protocol (total follicular and luteal phase) and minimum stimulation in patients with poor ovarian response in microinjection cases

Design

In this quasi-experimental randomized clinical trial, which will be conducted on 60 infertile women who come to the Taleghani Center. Women with poor ovarian response in the previous ART cycle will be selected to participate in the project, and in the new cycle a random number table will be used to randomize. Through which participants in this study were divided into two groups, under the luteal and follicular phase stimulation(Double stimulation) regimen or at minimal stimulation

Settings and conduct

In this quasi-experimental randomized clinical trial, which will be conducted on 60 infertile women who come to the Taleghani Center. Women with poor ovarian response in the previous ART cycle will be selected to participate in the project, and in the new cycle a random number table will be used to randomize. Through which participants in this study were divided into two groups, under the luteal and follicular phase stimulation(Double stimulation) regimen or at minimal stimulation

Participants/Inclusion and exclusion criteria

Cancellation of the previous cycle due to inadequate ovarian response, and after ovarian stimulation in the previous cycle, less than three follicles and after puncture were obtained less than an oocyte

Intervention groups

Participants in this study were divided into two groups, under the luteal and follicular phase stimulation(Double stimulation) regimen or at minimal stimulation

Main outcome variables

Number of follicles; number of recovered oocytes; number of canceled cycles; number of embryo-embryo grading; transmitted embryos; pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180908040964N1**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **retrospective**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

sedighe hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

Email address

shosseini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision The Effect of Minimal stimulation and double stimulation protocol in poor ovarian response in ICSI cycle		Medical Sciences
Public title Comparision The Effect of Minimal stimulation and double stimulation protocol in poor ovarian response in ICSI cycle		Street address Velenjak, Yaman St, Chamran highway
Purpose Treatment		City Tehran
Inclusion/Exclusion criteria Inclusion criteria: In these individuals, the previous cycle was canceled due to insufficient ovarian response. After ovarian stimulation in the previous cycle, less than three follicles and after puncture, less than one ovum were obtained. Exclusion criteria:		Province Tehran
Age From 20 years old to 38 years old		Postal code 1983969411
Gender Female		Approval date 2018-04-29, 1397/02/09
Phase 2-3		Ethics committee reference number IR.SBMU.RETECH.REC. 1397.486 کد اخلاق
Groups that have been masked • Participant • Investigator		Health conditions studied
Sample size Target sample size: 60		1
Randomization (investigator's opinion) Randomized		Description of health condition studied Patients with poor ovarian response
Randomization description We use the numerical random number table to choose the numbers, for example, if the sample size is two digits. First, select a two-digit number completely randomly, for example by placing the pencil tip, and then go ahead and select two-digit numbers to get the required number.		ICD-10 code N98.9
Blinding (investigator's opinion) Double blinded		ICD-10 code description Complication associated with artificial fertilization, unspecified
Blinding description This is double-blind study, that the participants do not know which of the two control or test groups belong, and also the observers (researchers) do not know who the group is.		Primary outcomes
Placebo Not used		1
Assignment Parallel		Description Number of follicles
Other design features		Timepoint From the tenth day of the cycle
Secondary Ids empty		Method of measurement sonography
Ethics committees		2
1 Ethics committee Name of ethics committee Ethics committee of Shahid Beheshti University of		Description Number of recovered oocytes
		Timepoint Oocyte recovery day
		Method of measurement observation
		3
		Description Number of canceled cycles
		Timepoint Oocyte recovery da
		Method of measurement observation
		4
		Description Number of embryo
		Timepoint 5 days after Oocyte recovery
		Method of measurement

observation

5

Description

embryo grading

Timepoint

5 days after Oocyte recovery

Method of measurement

observation

6

Description

Transmitted embryos

Timepoint

Transfer day

Method of measurement

observation

7

Description

Pregnancy rate

Timepoint

Two weeks after transfer

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: In a double-stimulation protocol based on the Shanghai protocol, Qualified women entered the study in the first phase from the third day of the monthly cycle will receive a daily dose of 25 mg cholomifen citrate for up to a stimulation day. At the same time, letrozole at a dose of 2.5 mg per day from the third day for four days at 150 units, every other day will start. And will receive HMG on the 10th day. When at least 3 follicles have reached 18 mm or a follicle reached 20 mm, the triggering of oocyte with an GNRH agonist will start. 32 to 36 hours after an agonist GNRH injection search and retrieve oocytes from transvaginal sonography will begin and follicles less than 10 mm will remain to second phase in the luteal phase. After ultrasonography, the second phase of stimulation depends on presence of at least 2 antral follicles with a size of 2 to 8 mm. At this stage 225 Unit HMG with 2.5 mg Letrozole is prescribed daily from the day of recovery of oocyte or one day later. And when the dominant follicle reached 12mm, Letrozole is discontinued and daily administration of medroxyprogesterone acetate at a dose of 10 mg for 3 days will continue for patients with follicles up to 14 cm. And when at least 3 follicles have reached 18 mm or a follicle reached 20 mm, the triggering of oocyte with an GNRH agonist will start

again.

Category

Treatment - Drugs

2

Description

Intervention group: In the minimum protocol, colomibsin citrate is prescribed from day 2 to day 5 of the monthly cycle with a dose of 100 mg / day. From day four, 150 HMG units are prescribed. The GNRH antagonist is administered when the dominant follicle reaches 13 or higher and continues until the final trigger day. The ovulation stimulation is performed when the dominant follicle reaches 17 mm. In this HCG recombinant mcg is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

IVF Infertility and IVF ward of Talghani hospital

Full name of responsible person

Sedigh Hosseini

Street address

Yaman St., Velenjak, Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farah Farzand

Street address

Shahid Madani Avenue, Imam Hussein Hospital, 3rd Floor, Women's Prevention Research Center

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M.amirisiavashani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sediqueh Hosseini

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

In this study, the results of the study based on the initial outcome Will be shared. All of the data can be shared

after unidentifiable Participants
When the data will become available and for how long
Without restriction
To whom data/document is available
All researchers
Under which criteria data/document could be used

With permission from the author responsible
From where data/document is obtainable
Email to author responsible
What processes are involved for a request to access data/document
Email to author responsible
Comments