Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparision 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

Public title
Comparision The Effect of Minimal stimulation and double stimulation protocol in poor ovarian response in ICSI cycle
Purpose
Treatment
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:
Age
From **20 years** old to **38 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
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.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak, Yaman St, Chamran highway
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2018-04-29, 1397/02/09
Ethics committee reference number
IR.SBMU.RETECH.REC. 1397.486 کد اخلاق

Health conditions studied

1

Description of health condition studied
Patients with poor ovarian response
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
Number of follicles
Timepoint
From the tenth day of the cycle
Method of measurement
sonography

2

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 stimilation 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 follicules 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 stimulition depends on presence of at least 2 anthral 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 follicules 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
Sediqeh Hosseini
Street address
Yaman St., Velenjak, Chamran highway
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 2558
Email
shosseini@sbmu.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7758 2543
Email

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

Sediqeh Hosseini

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Taleghani hospital, Yaman st., Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 2558

Email

shosseini@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sediqeh Hosseini

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Taleghani hospital, Yaman st., Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 2558

Email

shosseini@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sediqeh Hosseini

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Taleghani hospital, Yaman st., Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 2558

Email

shosseini@sbmu.ac.ir

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