Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The Evaluation of The Effects of Mild Ovarian Stimulation on IVF(in vitro fertilization) Results In Comparison With Conventional Method ,The Infertility Center Hospital Patients,2012-2013

Protocol summary

Summary

Objective: The aim of this clinical trial was to compare the therapeutic effects of two ovarian stimulation methods (i.e. mild and conventional) on IVF outcomes. Study design: Inclusion criteria : women between 18 and 35 years of age with regular menses who were undergoing their first IVF. Exclusion criteria :established systemic disease and repeated abortions. The target population consisted of 204 female patients presenting to the infertility center. Patients were entered into the study after thorough evaluation and informed consent. Patients were randomly divided into two groups using a computer. Method: Patients were randomly divided into two groups of A and B. Both groups underwent treatment with gonadotropins. However, patients in the former group were given GNRH agonists, while GNRH antagonists and clomiphene citrate were administered to their counter parts in group B. Interventions: In group A, a conventional ovarian stimulation method was applied in that patients were given Superfact 500 micrograms SQ from day 21 of their menstrual cycle followed by a reduction in dose to 250 micrograms per day on the 3rd day of the cycle together with recombinant FSH at 225-150 IU for stimulation. As for group B, mild ovarian stimulation using 100mg of clomiphene citrate was initiated from days 3 to 7 of the menstrual cycle. Gonadotropin-induced stimulation was begun on day 5 at a dose of 75 IU and the course was followed by a control ultrasound exam on day eight. In both groups, follicles were obtained for IVF or ICSI using transvaginal ultrasonic guided puncture 34-36 hours after the injection of HCG. Outcomes: The primary outcomes were the determination of the number of chemical and clinical pregnancies, while secondary outcomes included evaluating the number of fetuses, the number of frozen fetuses, and possible complications (e.g. multiparities;implantation rates; and the OHSS syndrome).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030516858N1**
Registration date: **2014-04-01, 1393/01/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-01, 1393/01/12

Registrant information

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Sepideh Peyvandi
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of The Effects of Mild Ovarian Stimulation on IVF(in vitro fertilization) Results In Comparison With Conventional Method ,The Infertility Center Hospital Patients,2012-2013

Public title

Compare Two Different Methods of Ovarian Stimulation On Outcome of In Vitro Fertilization (IVF)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female patient age 18–35 years; presence of a regular ; proven ovulatory menstruation cycle with a length of 26–35 days, more that 5 million sperm in SA(semen analysis);body mass index (BMI) of 18–30 kg/m ; first IVF attempt . Exclusion criteria:established systemic disease ;ovary and Uterus abnormalities;repeated abortions.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Payambar Aazam Department, 18th kilometer of Sea Roud, SARI , MAZANDARAN , IRAN

City

Sari

Postal code

Approval date

2012-11-07, 1391/08/17

Ethics committee reference number

91-179

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female Infertility

Primary outcomes

1

Description

Increase Endometrial Thickness

Timepoint

2 Days After HCG Injection

Method of measurement

Sonography

2

Description

Increase Implantation

Timepoint

3 week

Method of measurement

Lab Test

3

Description

Increase Chemical Pregnancy

Timepoint

12 Day

Method of measurement

ß-hCG

4

Description

Increase Clinical Pregnancy

Timepoint

3 week

Method of measurement

Sonography

5

Description

Decrease Treatment Cost

Timepoint

Delivery Time

Method of measurement

Counting-RIALs

Secondary outcomes

1

Description
Decrease OHSS Syndrom
Timepoint
Delivery Time
Method of measurement
Counting

2

Description
Decrease of Multiple Pregnancy
Timepoint
Delivery Time
Method of measurement
Counting

3

Description
Increase Of Follicular Number
Timepoint
8 Day
Method of measurement
Counting

4

Description
Increase Of Ovoocyt Number
Timepoint
10 Days
Method of measurement
Counting

5

Description
Increase Of Embryo Freez
Timepoint
3week
Method of measurement
Counting

Intervention groups

1

Description
Control Group(group active control or standard) :The Cases in This Group Will Be Treated with Conventional Ovarian Stimulation .They Desensitized with OCP ,Sarting on 3th Cycle Day.in Menstrual Cycle 21th Day, They Were Injected 0.5 cc Superfact (GNRH-a),(S.C) and in 3th Day of Menstrual Bleeding The Dosage Was Changed Into The 0.25 cc (S.C) In The Patients. Ovarian Stimulation Was Started With 150–225 IU Recombinant FSH (r_FSH) S.C.
Category
Treatment - Drugs

2

Description
Patients in Group With New Treatment(mild Ovary Stimulation) Were Stimulated Clomiphene Citrate 100 mg From Cycle Day Three Through Seven and Continuous Gonadotropin Stimulation With Of r_FSH 75 IU Daily From Cycle Day 5.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic Of Emam Khomaini Hospital
Full name of responsible person
MRs soltani-Mrs rasouli
Street address
Emam Khomeini Hospital, Amir Mazandarani Street , SARI ,MAZANDARAN, IRAN
City
sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mr gholami
Street address
sari 18th km sea roud.payambar aazam department
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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

Mazandaran University of Medical Sciences
Full name of responsible person
Dr Sepideh Peyvandi
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cheif -Associated professor of Obstetric and Gynecology-fellowship of infertility
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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