

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of pregnancy rate in single versus double Intrauterine Insemination (IUI) when polycystic ovarian syndrome or unexplained, mild male factor infertility is present.

Protocol summary

Summary

The aim of this study is to compare of pregnancy rate of single intrauterine insemination (IUI) compared to double intrauterine insemination (IUI) when conditions of unexplained, mild male factor infertility or polycystic ovarian syndrome exist. This prospective and randomized clinical trial will be conducted on females who have engaged in sexual intercourse over a period of one year without contraceptives but failed to become pregnant and were referred to a private infertility center. A review of the medical history, verification of ovulation using progesterone serum level in the middle of the luteal phase, for confirming of opening of fallopian tubes using laparoscopy or histrosalpangography and anatomical study of uterus using ultrasonography will be performed on each female candidate. Hormonal assessing will be performed on the 3th day of menstrual cycle. Semen analysis will be performed on the male partner of each candidate. Induction of ovulation will be performed using (1) oral tablet, (2) injection of HMG and HCG or (3) both methods, based on the opinion of the physician. Candidates will enter into the study upon administering the first dose of HCG. Vaginal sonography will be performed on the 3rd day following induction of ovulation. Any female with an ovarian cyst greater than 15mm in diameter will exclude from the study. Subjects will be divided into single step or double step intrauterine insemination groups by block randomization. Single step IUI will be performed 36 hours after receiving HCG and double step IUI will be performed 18 hours and 40 hours after receiving HCG. Pregnancy Test (serum BHCG level) will be performed 14 days after IUI. Visual inspection of the Fetal Heart Rate (FHR) using transvaginal sonography will be performed at the 7th week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307231306N7**

Registration date: **2013-08-03, 1392/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-03, 1392/05/12

Registrant information

Name

Ziba Zahiri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

drzibazahiri@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Guilan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregnancy rate in single versus double Intrauterine Insemination (IUI) when polycystic ovarian syndrome or unexplained, mild male factor infertility is present.

Public title

Comparison of pregnancy rate in single versus double Intrauterine Insemination (IUI) when polycystic ovarian syndrome or unexplained, mild male factor infertility is present.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: base serum level of FSH<12 mlu/l; females with polycystic ovarian syndrome who have not become pregnant despite six times of ovulation induction and having a suitable ovum. Females whose male partners have unexplained, mild male factor infertility; have no severe medical illness; no obstruction in tubes; no uterine anomaly. Exclusion criteria: existence of less than 2 or more than 5 ovarian follicles; any severe medical illness; females with ovarian cysts greater than 15mm after 3rd day following menstruation (diagnosed using transvaginal sonography).

Age

From **35 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **580**

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**

Ethics Committee of Guilan University of Medical Sciences

Street address

Ethics Committee Guilan University of Medical Sciences. Gaz Square

City

Rasht

Postal code**Approval date**

2013-06-17, 1392/03/27

Ethics committee reference number

1920101206

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

Ovarian dysfunction

ICD-10 code

E28

ICD-10 code description

Polycystic ovarian syndrome

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

Pregnancy

Timepoint

14 days after IUI

Method of measurement

Serum BHCG level assessment

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

Pregnancy outcome

Timepoint

14 days after IUI

Method of measurement

Serum BHCG level assessment

2**Description**

Diagnosis of intrauterine pregnancy

Timepoint

7th week of pregnancy

Method of measurement

Fetal Heart Rate (FHR) (transvaginal sonography)

3**Description**

Frequency of complications (abortion, ectopic pregnancy, multifetal gestation)

Timepoint

Completion of treatment and follow up period

Method of measurement

Diagnosis of ectopic pregnancy and

Intervention groups

1

Description

Ovulation induction using (1) tablets containing clomiphene citrate and letrozole, (2) injections including HMG and HCG or (3) both tablets and injection followed by single step IUI at 36 hours after tablet/injection/both

Category

Treatment - Devices

2

Description

Ovulation induction using: (1) tablets containing clomiphene citrate and letrozole, (2) injections including HMG and HCG or (3) both tablets and injection followed by double step IUI at 18 hours and 40 hours after tablet/injection/both

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran

Full name of responsible person

Ziba Zahiri

Street address

Alzahra Hospital, Namjo Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Guilan University of Medical Sciences

Full name of responsible person

Abdolrasol Sobhani

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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

Vice Chancellor for Research, Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Romina Rashid Shomali

Position

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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