Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 loteual phase, for confirming of opening of fallopian tubes using laprascopy 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
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Guilan University of Medical Sciences
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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 mIu/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
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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
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Person responsible for updating data

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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