

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of controlled ovarian stimulation with clomiphen citrate HMG(Human menopausal gonadotropin) or clomiphen citrate rFSH(recombinant follicle stimulating hormon) in IUI(Intrauterine Insemination)cycles.

Protocol summary

Summary

Aim and background: 10 to 15% of couples in reproductive age is infertile; controlled ovarian stimulation and intrauterine insemination (COS+IUI) is a common therapeutic procedure among infertile couples (unexplained and male factor infertility).Despite the differences in gonadotropin type, content and activity and their widespread use, few studies compared these products. In this study we compare two COS regimens, Clomiphen Citrate + HMG(Human menopausal gonadotropin) and Clomiphen Citrate + rFSH(recombinant follicle stimulating hormon).Material and methods : This is a Randomized Clinical Trial with 82 Cycles in CC + HMG and 60 cycles in CC + rFSH group.Patients with mild male factor and unexplained infertility were randomized to receive CC+ HMG or CC + rFSH.COS was started on 3rd day after menstruation after the basal transvaginal ultrasonography(TV_USG) with 100 mg CC for 5 consecutive day and gonadotropin administration began on 7th day with 75 IU.(if ≥ 35 years old 150 IU was given)The cycles was monitored by TV_USG from the 9th day and then every other day. On the day that 1 or more follicles of ≥ 16 mm were seen,10'000 IU HCG was administered and 36 hours later IUI was performed.14 days after IUI β HCG level was checked.In case of pregnancy a TV_USG was performed at 7th week of gestation to confirm clinical pregnancy,all pregnancies were followed up to 12 weeks of gestation. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109163386N4**

Registration date: **2011-10-01, 1390/07/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-01, 1390/07/09

Registrant information

Name

Azam Azargoon

Name of organization / entity

Semnan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2009-06-18, 1388/03/28

Expected recruitment end date

2010-06-20, 1389/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of controlled ovarian stimulation with clomiphen citrate HMG(Human menopausal gonadotropin) or clomiphen citrate rFSH(recombinant follicle stimulating hormon) in IUI(Intrauterine Insemination)cycles.

Public title

Comparison of controlled ovarian stimulation with clomiphen citrate HMG(Human menopausal gonadotropin) or clomiphen citrate rFSH(recombinant follicle stimulating hormone) in IUI(Intrauterine Insemination) cycles.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: history of infertility of more than 1 year; women's age between 20 and 40 years old; documentation of normal ovulatory cycles; normal TSH and Prolactin level; normal reproductive hormones in the early follicular phase; patent tubes have been shown by HSG or laparoscopy; normal sperm count, motility and morphology according to the World Health Organization criteria(WHO 1992)in unexplained infertility and total motile sperm count more than 1 million in male factor infertility.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **142**

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

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij-blvd

City

Semnan

Postal code

Approval date

2009-06-17, 1388/03/27

Ethics committee reference number

2/3788/Ī

Health conditions studied

1

Description of health condition studied

Unexplained infertility

ICD-10 code

n97.9

ICD-10 code description

Female infertility, unspecified

2

Description of health condition studied

Male factor infertility

ICD-10 code

n46

ICD-10 code description

Oligospermia NOS

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

7 weeks of gestation

Method of measurement

Fetal heart activity with ultrasound

2

Description

Ongoing pregnancy rate

Timepoint

12 weeks of gestation

Method of measurement

Fetal heart activity with ultrasound

Secondary outcomes

1

Description

Mean of follicular size on the day of HCG administration

Timepoint

Day of occurrence of at least one ovarian follicle ≥ 16 mm in diameter

Method of measurement

Ultrasound

2

Description

Endometrial thickness on the day of HCG administration

Timepoint

Day of occurrence of at least one ovarian follicle ≥ 16 mm in diameter

Method of measurement

Ultrasound

3

Description

Total dose of gonadotropin

Timepoint

Day of occurrence of at least one ovarian follicle ≥ 16 mm in diameter

Method of measurement

Number of vials

4

Description

Duration of stimulation with gonadotropin

Timepoint

Day of occurrence of at least one ovarian follicle ≥ 16 mm in diameter

Method of measurement

Number of days gonadotropin was administered

5

Description

Number of dominant follicles on the day of HCG administration

Timepoint

Day of occurrence of at least one ovarian follicle ≥ 16 mm in diameter

Method of measurement

Number of dominant follicles

Intervention groups

1

Description

Ovarian cycle stimulation was started on the 3rd day of menstruation after the basal transvaginal ultrasound (TV-USG) with 100 mg CC for 5 consecutive days. The gonadotropin regimens adopted in each group was HMG 75 IU (Merional HP, Serono, Turkey), intramuscular, daily from day 7 of menstrual cycle. (If older than 35 years old 150 IU was given). TV-USG was started from day 9 of menstrual cycle every other day for follicular size tracing. The gonadotropin dose was continued until the occurrence of at least one ovarian follicle ≥ 16 mm in diameter, then HCG (Profasi, Serono, Turkey) 10'000 IU was administered intramuscularly to trigger final follicular maturation and IUI with a sperm swim-up procedure was performed 35-36 hours later with Wallace Artificial Insemination Catheter (UK) SMITHS. For prevention of OHSS ovulation was induced by 0.5 cc GnRH-a (superfact....) if there were ≥ 5 follicles with a diameter of ≥ 16 mm at the time of induction. The luteal phase was supported with 400 mg of vaginal progesterone suppository (Cyclogest, Actavis, UK) twice a day administered from the day of IUI for two weeks. A blood sample for β HCG (beta human chorionic gonadotropin) were obtained two weeks after IUI for pregnancy confirmation. A clinical pregnancy was determined by the visualization of an embryo with cardiac activity at 7 weeks of gestation in TV-USG. In case of pregnancy progesterone was continued till 12 weeks

of gestation.

Category

Treatment - Drugs

2

Description

Ovarian cycle stimulation was started on the 3rd day of menstruation after the basal transvaginal ultrasound (TV-USG) with 100 mg CC for 5 consecutive days. The gonadotropin regimens adopted was rFSH 75 IU (Gonal F, Serono, Turkey), subcutaneous from day 7 of menstrual cycle. (If older than 35 years old 150 IU was given) TV-USG was started from day 9 of menstrual cycle every other day for follicular size tracing. The gonadotropin dose was continued until the occurrence of at least one ovarian follicle ≥ 16 mm in diameter, then HCG (Profasi, Serono, Turkey) 10'000 IU was administered intramuscularly to trigger final follicular maturation and IUI with a sperm swim-up procedure was performed 35-36 hours later with Wallace Artificial Insemination Catheter (UK) SMITHS. For prevention of OHSS ovulation was induced by 0.5 cc GnRH-a (superfact....) if there were ≥ 5 follicles with a diameter of ≥ 16 mm at the time of induction. The luteal phase was supported with 400 mg of vaginal progesterone suppository (Cyclogest, Actavis, UK) twice a day administered from the day of IUI for two weeks. A blood sample for β HCG (beta human chorionic gonadotropin) were obtained two weeks after IUI for pregnancy confirmation. A clinical pregnancy was determined by the visualization of an embryo with cardiac activity at 7 weeks of gestation in TV-USG. In case of pregnancy progesterone was continued till 12 weeks of gestation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Street address

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Research deputy

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City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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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Full name of responsible person

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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