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 follicule 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 follicule 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≥16mm were sewen,10'000 IU HCG was administerd and 36 hours later IUI was performed.14 days after IUI βHCG 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

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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 follicule 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 follicule stimulating hormon) in IUI(Intrauterine Insemination) cycles.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: history of infertility of more than 1 year; wemon'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 follicule ≥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 follicule ≥16 mm in diameter
Method of measurement
Ultrasound

3

Description
Total dose of gonadotropin
Timepoint
Day of occurrence of at least one ovarian follicule ≥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 follicule ≥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 follicule ≥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 follicule ≥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 βHCG (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 follicule ≥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 βHCG (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
Imam Hosein Square
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Research deputy
Street address
Semnan University of Medical Sciences, Basij-blvd
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

Semnan University of Medical Sciences

Full name of responsible person

Marjan Bahrami

Position

Gynecolgy Resident

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

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Full name of responsible person

Azam Azargoon

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Associated professor, Fellowship of infertility

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Pathologist and Analyst

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Web page address

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