Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of four different protocols for ovarian stimulation including: hFSH, rFSH, HMG, sequential use of hFSH & rFSH on quality of oocyte and embryo

Protocol summary

Summary

The overall objective: Comparison of effect of four different protocols for ovarian stimulation including: hFSH, rFSH, HMG, sequential use of hFSH & rFSH on quality of oocyte and embryo Specific goals: 1-Compare duration of stimulation 2-Compare number of follicles with large and medium size 3- Compare the serum estadiol level on hCG day 4- Compare number of retrieved oocytes 5- Compare the quality of oocytes (MI, MII, GV) 6-Compare the quality of embryos (grade 1 to grade 4) 7- Compare number of transferred embryos Material methods: The patients who refer to Dena hospital and mother and child infertility center are refered to Gynecologist (in the center) according to inclusion and exclusion criteria, after taking informed permission. All the participants (160 persons) will be underwent down-regulation standard protocol with GnRH agonist (buserelin 0.4mg) , subcutaneously from day 21 of menstrual cycle. From day 2 of next cycle, after determination of desensitization (estradiol level less than 50 pg/ml, no follicle with 10 cm or more size, endometrial thickness less than 5mm) gonadotropins is started. The patients will be divided into four groups ,completely randomely and according to the numbered table. The first group(40 pt) will receive HP-HMG (menopur, ferring pharmaceuticals, Copenhagen Denmark) from day 2 to the hCG day. The second group(40 pt) will receive hFSH (Fostimon, IBSA, Geneva, Switzerland) from day 2 to the hCG day The third group(40 pt) will receive rFSH (Gonal-F, Sereno, Rome, Italy) from day 2 to the hCG day. The fourth group(40 pt) will receive hFSH (Fostimon, IBSA, Geneva, Switzerland) for six days and then continued with rFSH (Gonal-F, Sereno, Rome, Italy) to the hCG day. From the day 6, dosage of gonadotropins adjusted according to evaluation of stimulation with transvaginal sonography and serum estradiol, each 1-3 day Stimulation continued until there was at least two 17-18 mm follicles & some 14-16 mm follicles & appropriate estradiol level In the cases of ovary hyperstimulation that ovaries became grossly large , containing more than 15 follicles in medium (>15mm) & large (>16mm) size, high level of estradiol (>3500pg/ml), counseled with the patients aboute the risk of OHSS , and evaluated for sign and symptoms of OHSS Management of these patients was done according to instructions in Guideline of Infertility center of Shiraz University of Medical Siences , based on serum estrsdiol level and size of follicles. When a group of follicles became mature, 10000 IU hCG (Gonasi HP, IBSA, Italy) was administered for final step of maturation 34-36 hours after hCG administration, oocyte retrieval was done under guide of transvaginal sonography and evaluated for maturation. Immature oocytes with germinal vesicle within them belongs to GV group Immature oocytes in methaphase I without germinal vesicle or polar body belongs to MI group. Mature oocytes in methaphase II with polar body in previtteline space belongs to MII group After fertilization , IVF or ICSI was done (for each patient according to indication). Embryo scoring was done according to morphological features: Grade A: embryos with 8 blastomeres , equal size & without fragmentation Grade B: blastomers have equal size with mild to moderate fragmentation. Grade C: blastomers don’t have equal size with or without fragmentation. Grade D: blastomers with moderate to severe fragmentation , with or without equal size. 72 houres after fertilization, embryos transfered under guide of sonography. Pregnancy supported by intramuscular progesterone (50 mg/ml). Chemical pregnancy confirmed with rise of ß-hCG at day 12 (after embryo transfer), and clinical pregnancy by detecting gestational sac in 6th week sonography It should be mentioned that this study was assessor blind. (Intervention/Control): The first group(40 pt) received HP-HMG (menopur, ferring pharmaceuticals, Copenhagen Denmark) from day 2 to the hCG day. The second

group(40 pt) received hFSH (Fostimon, IBSA, Geneva, Switzerland) from day 2 to the hCG day. The third group(40 pt) received rFSH (Gonal-F, Sereno, Rome, Italy) from day 2 to the hCG day The fourth group(40 pt) received hFSH (Fostimon, IBSA, Geneva, Switzerland) for six days and then continued with rFSH (Gonal-F, Sereno, Rome, Italy) to the hCG day Primary outcome measure : quality and number of ovum and emberyo have received in each cycle

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408116541N7**
Registration date: **2014-09-16, 1393/06/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-09-16, 1393/06/25

Registrant information

Name
Bahia Namavar Jahromi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 1233 2365

Email address
namavarb@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of four different protocols for ovarian stimulation including: hFSH, rFSH, HMG, sequential use of hFSH & rFSH on quality of oocyte and embryo

Public title

comparison of ovulation induction with different gonodotropins

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: Unexplained infertility؛ Male infertility Inclusion criteria: Ovarian disease؛ Previous failure of ovulation induction with FSH Age more than 40 years old؛ FSH more than 10mIU/ml؛ AFC less than 5 in both ovaries؛ AMH less than 1ng/ml

Age

To **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Science Researching، Shiraz univercity of Medical Science

Street address
Shiraz University Of Medical Sciences

City
Shiraz

Postal code

Approval date

2014-01-21, 1392/11/01

Ethics committee reference number

ct-p-92-7249

Health conditions studied

1

Description of health condition studied

Unexplained infertility and male infertility

ICD-10 code

N97.9

ICD-10 code description

female infertility, unspecified

Primary outcomes

1

Description
- quality and number of ovum and emberyo have received in each cycle

Timepoint
- On the day of oocyte retrieval, three days after oocyte fertilization

Method of measurement
Measuring number and quality of oocytes on the day of pick up in lab by an embryologist under microscope (GV , MI , MII) and quality of emberyo also by the same embryologist due to kind of cell division (Grade I , II , III , IV).

Secondary outcomes

1

Description
- Biochemical pregnancy, clinical pregnancy

Timepoint
- 12 days after embryo transfer, 6 weeks after embryo transfer

Method of measurement
ßhCG titer, detecting gestational sac by sonography

Intervention groups

1

Description
The first group(40 pt) received HP-HMG (menopur, ferring pharmaceuticals, Copenhagen Denmark) from day 2 to the hCG day.

Category
Treatment - Drugs

2

Description
The second group(40 pt) received hFSH (Fostimon, IBSA, Geneva, Switzerland) from day 2 to the hCG day.

Category
Treatment - Drugs

3

Description
The third group(40 pt) received rFSH (Gonal-F, Sereno, Rome, Italy) from day 2 to the hCG day

Category
Treatment - Drugs

4

Description
- The fourth group(40 pt) received hFSH (Fostimon, IBSA, Geneva, Switzerland) for six days and then continued with rFSH (Gonal-F, Sereno, Rome, Italy) to the hCG day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mother & Child Hospital

Full name of responsible person
Dr solmaz rezaei

Street address
Ghadir mother and child hospital and Dena hospital

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
dr basire hashemi

Street address
Shiraz University of Medical Sciences ,Zand Street

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
shiraz University of Medical Sciences

Full name of responsible person
Dr solmaz rezaei

Position
Resident Of GYN

Other areas of specialty/work

Street address
Shiraz University of Medical Sciences ، zand street

City

Shiraz
Postal code
Phone
+98 71 1227 9715
Fax
Email
solmaz_rz@yahoo.coms.kharati@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Bahia Namavar Jahromi
Position
Professor of Obstetrics & GYN, Fellowship Infertility
Other areas of specialty/work
Street address
Shiraz University of Medical Science , Zand Street
City
Shiraz
Postal code
Phone
+98 71 1227 9715
Fax
Email
namavarb@sums.ac.irs.kharati@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Science
Full name of responsible person
Dr solmaz rezaei
Position
Resident of GYN
Other areas of specialty/work
Street address
Shiraz University of Medical Science ، Zand Street
City
Shiraz
Postal code
Phone
+98 71 1227 9715
Fax
+98 71 1227 9715
Email
solmaz_rz@yahoo.coms.kharati@yahoo.com
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