

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of different medication protocols for in vitro fertilization to induce controlled ovarian stimulation on expression of Gremlin1 (GREM1), Hyaluronic acid Synthetase2 (HAS2) and Prostaglandin synthetase2 (PGS2) genes as markers of oocyte maturation in granulosa cells

Protocol summary

Summary

Objective: Comparison of 4 protocols of ovulation induction in IVF for the expression of GREM1, HAS2 and PGS2 genes in granulosa cells as a probable determinant of oocyte maturation. Study design: The study will be performed on 200 infertile couples that need IVF with unexplained cause or male factor . The ovaries will be suppressed from the 21th day of the previous cycle and gonadotropin will be started from the 2nd day of the cycle up to the day of HCG injection using 4 methods. Group 1: will receive highly purified-human HMG, group 2: human-FSH, group 3: recombinant-FSH, group 4: human-FSH for 6 days followed by recombinant-FSH, respectively. All of the drugs will be started with the dose of 225 IU/day. The dose can be changed if needed after ultrasound scanning. Randomization will be performed according to the number of entrance of the cases in the study. HCG will be injected when follicles are mature. Estradiol level on HCG day, number of harvested Follicles and their quality, number and grade of embryos and clinical pregnancy rate will be evaluated. Granulosa cells will be separated and freezed in liquid nitrogen. The quantity of GREM1, HAS2 and PGS2 genes expression on granulose cells will be evaluated by PCR method and will be compared to the outcome measures between the four methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201046541N2**
Registration date: **2012-02-10, 1390/11/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-10, 1390/11/21

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, Infertility research center

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different medication protocols for in vitro fertilization to induce controlled ovarian stimulation on expression of Gremlin1 (GREM1), Hyaluronic acid Synthetase2 (HAS2) and Prostaglandin synthetase2 (

PGS2) genes as markers of oocyte maturation in granulosa cells		Ethics committee of Shiraz University of Medical Sciences	
Public title		Street address	
Comparison of different medication protocols for induction of ovarian in the cycles of in vitro fertilization on expression of GREM 1, HAS2 and PGS2 genes as determinants of oocyte development		Shiraz University of Medical Sciences , Zand Street	
Purpose		City	
Treatment		Shiraz	
Inclusion/Exclusion criteria		Postal code	
Inclusion criteria: Infertility with male factor or with unexplained cause. Exclusion criteria: all the cases with known female factor.		Approval date	
Age		2011-12-19, 1390/09/28	
From 20 years old to 38 years old		Ethics committee reference number	
Gender		CT-90-5873	
Female		3	
Phase		Ethics committee	
2		Name of ethics committee	
Groups that have been masked		Ethics committee of Shiraz University of Medical Sciences	
No information		Street address	
Sample size		Shiraz University of Medical Sciences, Zand street	
Target sample size: 200		City	
Randomization (investigator's opinion)		Shiraz	
Randomized		Postal code	
Randomization description		Approval date	
Blinding (investigator's opinion)		2011-12-18, 1390/09/27	
Single blinded		Ethics committee reference number	
Blinding description		CT-90-5875	
Placebo		Health conditions studied	
Not used		1	
Assignment		Description of health condition studied	
Parallel		male infertility	
Other design features		ICD-10 code	
		N46	
		ICD-10 code description	
		Male infertility	
Secondary Ids		2	
empty		Description of health condition studied	
		Female infertility	
Ethics committees		ICD-10 code	
1		N97.9	
Ethics committee		ICD-10 code description	
Name of ethics committee		Female infertility, unspecified	
Ethics committee of Shiraz University of Medical Sciences		Primary outcomes	
Street address		1	
Shiraz University of Medical Sciences, Zand street		Description	
City		Number of oocytes	
Shiraz		Timepoint	
Postal code		At the time of Harvesting the oocytes	
Approval date		Method of measurement	
2011-12-19, 1390/09/28		Counting the oocytes	
Ethics committee reference number		2	
CT-90-5874		Description	
2			
Ethics committee			
Name of ethics committee			

quality of oocytes
Timepoint
At the time of oocyte retrieval
Method of measurement
based on quality grading(GV-MI-MII)

3

Description
embryo count
Timepoint
3 days after oocyte retrieval
Method of measurement
microscopic evaluation

4

Description
Evaluation of expression of HAS2 Gene
Timepoint
after oocyte retrieval
Method of measurement
Polymerase Chain Reaction (PCR)

5

Description
quantity of GREM1 expression
Timepoint
at the time of oocyte retrieval
Method of measurement
PCR test

6

Description
Evaluation of expression of PGS2 Gene
Timepoint
after oocyte retrieval
Method of measurement
Polymerase Chain Reaction (PCR)

Secondary outcomes

empty

Intervention groups

1

Description
group 1: highly purified-human HMG starting with the dose of 225 IU/day
Category
Treatment - Drugs

2

Description
group 2: human-FSH starting with the dose of 225 IU/day
Category
Treatment - Drugs

3

Description
group 3: recombinant-FSH starting with the dose of 225 IU/day
Category
Treatment - Drugs

4

Description
group 4: human-FSH for 6 days followed by recombinant-FSH starting with 225 IU/day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghadir hospital for mother and child
Full name of responsible person
Dr. Mohammad Ebrahim Parsanejhad
Street address
Shiraz university of Medical Sciences, Infertility research center
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz university of Medical Sciences, Infertility research center
Full name of responsible person
Dr. Jhale Zolghadr
Street address
Ghadir Hospital for Mother and Child, Infertility research center, Shiraz university of Medical Sciences
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, Infertility research center
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, Infertility
research center
Full name of responsible person
Dr. Bahia Namavar Jahromi
Position
Associate professor in Shiraz University of Medical
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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