Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison the effect of Recombinant HCG and urinary HCG in infertile women at IVF cycle

Protocol summary

Study aim
increasing of mature oocytes

Design
A randomized, clinical trial with a parallel control group design of 200 patients, enrolled between January 2009 to July 2010, and followed 3 weeks after positive βHCG.

Settings and conduct
Yazd Research and Clinical Center for infertility affiliated to Shahid Sadoughi University of Medical Sciences

Participants/Inclusion and exclusion criteria
Inclusion criteria: regular menstrual cycles; age<38 years old; FSH<10 IU/L; BMI<30kg/m2 Exclusion criteria: history of metabolic or endocrine disorder; history of pelvic surgery; severe male factor infertilitywhich was defined as severe oligospermia (<5million sperm/ml),asthenospermia (5% progressive motility),or teratospermia (4% normal forms by strict criteria).

Intervention groups
Patients undergo pituitary desensitization with Decapeptyl 0.1 mg/day starting in the mid luteal phase and was continued until the day of the administration of HCG. Treatment with Gonal-F is started at the second day of menstruation .The ovarian response is monitored by vaginal sonography and the dose is adjusted accordingly triggering of final follicular maturation with r-HCG (interventional group) or U- HCG (control group) is performed in the evening. Oocyte is retrieved by follicular aspiration 34-36 hrs after r-hcG or U-hcG. Up to three embryos are replaced in the uterine cavity on day 3after ovum pick up. Luteal phase support is designed by 100mg progesterone intra muscular injection per day. After 14 days of embryo transfer βHCG is checked and clinical pregnancy is documented by vaginal sonography at 3weeks after positive βHCG.

Main outcome variables
تعداد تخمک بالغ

General information

Reason for update
update as result

Acronym
IVF

IRCT registration information
IRCT registration number: **IRCT201107034339N2**
Registration date: **2011-08-09, 1390/05/18**
Registration timing: **retrospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **2**

Registration date
2011-08-09, 1390/05/18

Registrant information

Name
Elham Rahmani

Name of organization / entity
Bushehr University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Yazd research and clinical center for infertility

Expected recruitment start date
2009-01-01, 1387/10/12

Expected recruitment end date
2009-12-30, 1388/10/09

Actual recruitment start date
2009-01-01, 1387/10/12

Actual recruitment end date
2009-12-30, 1388/10/09

Trial completion date
2010-07-30, 1389/05/08

Scientific title
comparison the effect of Recombinant HCG and urinary HCG in infertile women at IVF cycle

Public title
comparison the effect of two kind of HCG in IVF cycle
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
regular menstrual cycles age<38 years old FSH<10 IU/L BMI<30kg/m2
Exclusion criteria:
history of metabolic or endocrine disorder history of pelvic surgery severe male factor infertilitywhich was defined as severe oligospermia (<5million sperm/ml),asthenospermia (5% progressive motility),or teratospermia (4% normal forms by strict criteria).
Age
To **38 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Actual sample size reached: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
camputerized randomization by opening sealed envelopes
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
yazd research and clinical center for infertility
Street address
Boali Street, Safaieh, Yazd, Research and clinical center
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2009-02-01, 1387/11/13
Ethics committee reference number
2692

Health conditions studied

1

Description of health condition studied
female infertility
ICD-10 code
N97
ICD-10 code description
ناباروری زنان

Primary outcomes

1

Description
number and maturity of oocyte
Timepoint
ovum pick up
Method of measurement
by microscope

Secondary outcomes

1

Description
chemical pregnancy
Timepoint
14 days after embryo transfer
Method of measurement
blood

Intervention groups

1

Description
Intervention group: Patients undergo pituitary desensitization with Decapeptyl 0.1 mg/day (Decapeptyl® 0.1 mg, Ferring, Germany)starting in the mid luteal phase and was continued until the day of the administration of HCG. Treatment with Gonal-F(Gonal-F, Serono, Aubnne, Switzerland) is started at the second day of menstruation .The ovarian response is monitored by vaginal sonography and the dose is adjusted accordingly triggering of final follicular maturation with r-HCG (Ovidrel)(interventional group) is performed in the evening. Oocyte is retrieved by follicular aspiration 34-36 hrs after r-hcG or U-hcG. Up to three embryos are replaced in the uterine cavity on day 3after ovum pick up. Luteal phase support is designed by 100mg

progesterone intra muscular injection per day. After 14 days of embryo transfer βHCG is checked and clinical pregnancy is documented by vaginal sonography at 3weeks after positive βHCG.

Category

Treatment - Drugs

2

Description

Patients undergo pituitary desensitization with Decapeptyl 0.1 mg/day (Decapeptyl® 0.1 mg, Ferring, Germany)starting in the mid luteal phase and was continued until the day of the administration of HCG. Treatment with Gonal-F (Gonal-F, Serono, Aubnne, Switzerland) is started at the second day of menstruation .The ovarian response is monitored by vaginal sonography and the dose is adjusted accordingly triggering of final follicular maturation with U- HCG (control group) (pregnyl, ® organon, oss, Netherlands) is performed in the evening. Oocyte is retrieved by follicular aspiration 34-36 hrs after r-hcG or U-hcG. Up to three embryos are replaced in the uterine cavity on day 3after ovum pick up. Luteal phase support is designed by 100mg progesterone intra muscular injection per day. After 14 days of embryo transfer βHCG is checked and clinical pregnancy is documented by vaginal sonography at 3weeks after positive βHCG.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd research and clinical center for infertility

Full name of responsible person

Dr. Maryam Eftekhar

Street address

Boali street, Safaieh, Yazd, Research and clinical center for infertility

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Research & Technology

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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

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Maryam Eftekhar

Position

Obestetrics and Gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Full name of responsible person
Dr. Maryam Eftekhar
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Information on the main outcome
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
Editor-in-Chief
Under which criteria data/document could be used
use in the retrospective study
From where data/document is obtainable
Yazd research and clinical center for infertility
What processes are involved for a request to access data/document
Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, request is referred to the research experts and then get the data.
Comments

Trial results

Please tick if results have been published
Yes
Summary result posting date
2021-03-05, 1399/12/15
Table of baseline comparison

Table I

Basic characteristic of patients undergoing ICSI

Variable	rHCG (group I) (n=100)	uHCG (group II) (n=100)	p-value
Age(year)	29.63 ± 4.85	29.30 ± 4.89	0.637
Duration of infertility (years)	9.01 ± 6.66	8.98 ± 7.45	0.988
Basal FSH(IUI/L)	7.65 ± 3.62	6.75 ± 3.35	0.125
Infertility causes	0.382(**p-value)**		
	Male factor (%)	41 (41)	43 (43)
	Tubal factor (%)	6 (6)	11 (11)
	Unexplained factor (%)	25 (25)	20 (20)
	Mild endometriosis (%)	4 (4)	4 (4)
	Mixed (%)	13 (13)	6 (6)
	Ovarian factor (%)	10 (10)	16 (16)

Parameters expressed as mean±SD or percentages, as appropriate.

Participant flow diagram

Analysed (n=100)

Excluded from analysis (give reasons) (n=0)

Analysed (n= 100)

- Excluded from analysis (give reasons) (n= 0)

Assessed for eligibility (n=200)

Lost to follow-up (give reasons) (n= 0)

- Discontinued intervention (give reasons) (n=0)

Allocated to intervention (n= 100)

- Received allocated intervention (n= 100)
- Did not receive allocated intervention (give reasons) (n= 0)

Lost to follow-up (give reasons) (n= 0)

- Discontinued intervention (give reasons) (n= 0)

Allocated to intervention (n= 100)

- Received allocated intervention (n=100)
- Did not receive allocated intervention (give reasons) (n= 0)

Excluded (n= 0)

- Not meeting inclusion criteria (n=0)
- Declined to participate (n=0)
- Other reasons (n=0)

Randomized (n=200)

CONSORT 2010 Flow Diagram

Table of variable outcomes' results

Cycle characteristic and ICSI outcome

Variable	rHCG (group I) (n=100)	uHCG (group II) (n=100)	p-value
Duration of stimulation(d)	11.24 ± 2.26	11.33 ± 1.90	0.753
Dose of FSH used (IU)	2028 ± 680	2154 ± 894	0.267
No of follicle >14 mm	12.34 ± 12.5	11.81 ± 671	0.716
No. of retrieved oocytes	9.75 ± 6.65	9.64 ± 7.29	0.920
No. of mature oocytes	8.34 ± 5.27	8.27 ± 6.44	0.935
Maturation rate of oocytes	87.99%	86.25%	0.543
No. of transferred embryos	2.30 ± 0.90	2.09 ± 1.15	0.194
Fertilization rates	58.58%	60.58%	0.666
Clinical pregnancy rates	34%	39%	0.310
Abortion (%)	4 (11.76%)	5 (12.8%)	1.000
Mild to moderate OHSS (%)	7 (7%)	8 (8%)	1.000
Endometrial thickness	9.49 ± 1.63	9.82 ± 1.59	0.221

Parameters expressed as mean ± SD or percentages, as appropriate.

Table of adverse events

NO

First publication date

empty

Abstract of published paper

Background: Human chorionic gonadotropin (HCG) has been used as a replacement for the mid-cycle luteinizing hormone (LH) surge for several years. The recent arrival of recombinant DNA technology has made recombinant HCG (rHCG) accessible. Objective: To assess efficacy of rHCG compared to urinary HCG (uHCG) for triggering of ovulation and induction of final oocyte maturation in assisted reproductive cycles. Materials and Methods: 200 patients who were candidate for ICSI were randomly divided in two groups. In group I (rHCG), patients received 250µg of rHCG for final oocyte maturation, and in group II (uHCG) the patients received 10000 IU of uHCG. Measured outcomes were number of retrieved oocyte and mature oocyte, maturation rate of oocyte, fertilization rate and clinical pregnancy rate. Results: The rates of oocyte maturity were similar in both groups. Fertilization rate was similar in two groups (58.58% in rHCG group versus 60.58% in uHCG group p=0.666). The clinical pregnancy rate per cycle was similar in both group 34.0% in rHCG group versus 39% in uHCG group (p=0.310). Conclusion: We demonstrated that rHCG is as effective as uHCG, when it is used for final oocyte maturation in ICSI cycles. The numbers of retrieved oocyte and maturation rates were similar in both groups; also fertilization and clinical pregnancy rates were similar.