Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The evaluation of intrauterine HCG injection in oocyte retrieval day, in Assisted Reproductive Technique(ART) outcome

Protocol summary

Study aim

The evaluation of intrauterine HCG injection in oocyte retrieval day, in Assisted Reproductive Technique(ART) outcome

Design

Two arm parallel group randomised controlled clinical trial without blinded, with sample size 112

Settings and conduct

Infertile patients referring to Afzalipour Hospital infertility who enter the IVF / ICSI cycle, in intervention group, after oocyte retrieval, the speculum is placed and HCG is injected into the uterus with a catheter of IUI. In the control group, the substance is not injected into the uterus. The oocytes of the two groups are fertilized with IVF / ICSI and embryos transfered three days after oocyte retrieval . Chemical pregnancy is measured by measuring BHCG two weeks after embryo transfer and clinical pregnancy by ultrasound and observing the fetal heart rate 2-3 weeks after the positive pregnancy test.

Participants/Inclusion and exclusion criteria

Infertile women who are referred to the Afzalipour Infertility Center in Kerman and have inclusion criteriaare enrolled in the study. Inclusion criteria: Age less than 40 years Exclusion criteria: Age older than 40 years, azospermia, uterine leiomyoma with endometrial pressure, endometriosis, Recurrent implantation failure: failure to achieve a clinical pregnancy after transfer of at least three good-quality embryos, Endocrine disease, Hydrosalpinx

Intervention groups

In the intervention group, the hCG ampoule is injected into the uterine cavity on retrieval day. In the control group, no drug is injected into the uterine cavity.

Main outcome variables

Implantation rate; Chemical pregnancy rate; Clinical pregnancy rate; Abortion rate;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024335N3**
Registration date: **2018-07-07, 1397/04/16**
Registration timing: **prospective**

Last update: **2018-07-07, 1397/04/16**
Update count: **0**

Registration date

2018-07-07, 1397/04/16

Registrant information

Name
robabe hoseinisadat
Name of organization / entity
infertility institute center of shahid sadughi
Country
Iran (Islamic Republic of)
Phone
+98 35 3824 7085
Email address
robabehoseini@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The evaluation of intrauterine HCG injection in oocyte retrieval day, in Assisted Reproductive Technique(ART) outcome

Public title
intrauterine HCG in infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertility Age less than 40 years Female
Exclusion criteria:
Age older than 40 years azospermia uterine leiomyoma with endometrial pressure endometriosis Recurrent implantation failure: failure to achieve a clinical pregnancy after transfer of at least three good-quality embryos Endocrine disease Hydrosalpinx
Age
To **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
simple ,individual, table of random numbers randomization
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
Ethics Committee of Kerman University of Medical Sciences
Street address
Ibn Sina Street, Jihad Boulevard, Somayeh Road (Tahmasebabad)
City
kerman
Province
Kerman
Postal code
7619813159
Approval date
2018-06-26, 1397/04/05
Ethics committee reference number
IR.KMU.REC.1397.070

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
Chemical pregnancy
Timepoint
14 days after embryo transfer
Method of measurement
Measurement of serum beta-HCG

Secondary outcomes

1

Description
Abortion rate
Timepoint
Before the 20th week of pregnancy
Method of measurement
Contact patients at the 20th week of pregnancy

2

Description
Implantation rate (the number of gestational sacs divided by the number of transferred embryos)
Timepoint
Five weeks after embryo transfer
Method of measurement
Transvaginal ultrasound

3

Description
Clinical pregnancy
Timepoint
Five weeks after embryo transfer
Method of measurement
Transvaginal ultrasound

Intervention groups

1

Description
In the intervention group, infertile patients in IVF or microinjection cycle receive routine treatment until the day of oocyte retrieval. On oocyte retrieval day that performed with general anesthesia, after oocyte puncture, 1000 units of Pooyesh Darou PDP PREG HCG, with a volume of one cc, injected into the uterine cavity, with Intrauterine insemination Catheter.

Category
Treatment - Drugs

2

Description
In the control group, the drug administration, oocyte retrieval and embryo transfer are performed routinely and no additional drug is injected into the uterus.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Afzalipour Infertility Center

Full name of responsible person
Dr Robabe Hosseinisadat

Street address
Imam Khomeini Highway, Afzalipour Hospital

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kerman

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Phone
+98 34 3132 8486

Email
robabehosseinisadat@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Research Assistant, Kerman University of Medical Sciences

Street address
Ibn Sina Street, Jihad Boulevard, Somayeh Road (Tahmasebabad)

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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
Kerman University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Kerman University of Medical Sciences

Full name of responsible person
robabehosseinisadat

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Imam Khomeini Highway, Afzalipour Hospital

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Email
robabehosseinisadat@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
robabe hosseinisadat

Position
Assistant Professor Assistant Definitions of assistant

noun a person who ranks below a senior person

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The final result of the study will be published and there is no need to share individual participants' data.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available