

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 transferred 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 criteria are 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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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 (Tahmasebad)

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7619813159

Phone

+98 34 3226 3815

Email

robabehosseinisadat@yahoo.com

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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7616913911

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Fax

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

Street address

Imam Khomeini Highway, Afzalipour Hospital

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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

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

robabe hosseinisadat

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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