

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Randomised clinical trial of comparison between with and without atraumatic hysteroscopy on the improvement of endometrial receptivity on the shariati hospitals patient in 1394

Protocol summary

Summary

The aim of study :Compare Clinical pregnancy rates for controlled ovarian stimulation in IVF cycles with and without hysteroscopy 250 patients with primary infertility with regular menses under the age of 40 years who meet all the inclusion criteria After providing adequate explanations by the investigators and after patients acceptance will be entered to the study. The patients will be divided between two group randomly. Trans vaginal sonography (TVS) will be done for all patients in 1-3 cycle days . Ovarian stimulation will be done with antagonist regimen in two groups with recombinant 225 IU FSH daily, the dose will adjusted according to the ovarian response in TVS. The GnRH antagonist will start when the follicles become 14 mm in diameter. The final oocyte maturation will be achieved by the administration of HCG 10000 IU when 3 follicles become 17mm in diameter. Oocyte retrieval will be carried out 36 hours after HCG administrations. Embryo transfer will be performed on day 3 after oocyte retrieval and two grade 1 embryos will be transferred. Luteal phase supplementation consist of 3 suppository progesterone will be started the day after oocyte retrieval and will be continued to 7 weeks of gestation. For patients in the intervention group uterine cavity irrigation with normal saline in an outpatient setting with or without mild sedation will be done by doing hysteroscopy in the days 5-7 of stimulation cycle . After 2 and 4 weeks of embryo transfer chemical and clinical pregnancy will be evaluated by BHCG test and TVS respectively.

General information

Acronym

cycle hysteroscopy

IRCT registration information

IRCT registration number: **IRCT2016011022795N2**

Registration date: **2016-03-04, 1394/12/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-04, 1394/12/14

Registrant information

Name

Marzieh Ghasemi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5581

Email address

drghasemi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised clinical trial of comparison between with and without atraumatic hysteroscopy on the

improvement of endometrial receptivity on the shariati hospitals patient in 1394

Public title

evaluation of hysteroscopic effect on endometrial receptivity of the patients in the IVF cycle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:regular mense;age less than 40;BMI=19-30;without any prior hysteroscopy examination or previous IVF or ICSI; with a normal Transvaginal sonography (TVS) (in the day 2-3 same cycle);normal hystrosalpingo graphy (HSG) (between 6to24 mounths) . Exclusion criteria : recurrent miscamiage (3 or more miscarriage); inter menstrual bleeding; any doubt about uterine cavity abnormality; server male factor request to PESA or TESE; patients with poly cystic ovary syndrome or endometriosis ;hydrosalpinx ;ovarian cyst ; cancellation of the same cycle for any reason

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **250**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

central building of Tehran University of Medical Sciences ,keshavarz BLV,Tehran,Iran

City

Tehran

Postal code

1417614411

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.TUMS.REC.1394.1598

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.0,N97.

ICD-10 code description

Female infertility associated with anovulation, Female infertility of tubal origin, Female infertility of other origin, Female infertility, unspecified,

Primary outcomes

1

Description

clinical pregnancy rate in two groups

Timepoint

4 weeks after embryo transfer transvaginal sonography will be done and gestatinal sac will be evaluated

Method of measurement

Find gestational sac on transvaginal sonography

Secondary outcomes

1

Description

chemical pregnancy rate in two group ,abortion , implantation rate in two groups

Timepoint

two weeks after transfer for biochemical pregnancy,4weeks for clinical pregnancy,12 weeks after transfer for abortion,two weeks after transfer for implantation rate

Method of measurement

BHCG for biochemical ,trans vaginal sonography for clinical,physical examination and trans vaginal sonography for abortion ,trans vaginal sonography for implantation

Intervention groups

1

Description

Performing hysteroscopy in the 5-7 days of the IVF cycle treatment and uterine irrigation with normal saline in the patients in intervention group . For patients in the control group did not add any intervention.

Category

Treatment - Other

2

Description

In the control group the traditional IVF cycle will be done without any additional intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shriati hospital,Infertility ward

Full name of responsible person

Dr Marzieh Ghasemi,fellowship of infertility

Street address

Tehran,Jalal-Al -Ahmad BLV crossed north kargar,Shariati hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ashraf Alyacin

Street address

Tehran, Keshavarz Blvd, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences,infertility ward

Full name of responsible person

Marzieh Ghasemi

Position

fellowship in infertility

Other areas of specialty/work

Street address

Shariati Hospital , Jalal-Al-Ahmad BLV intersection Kargar shomali,Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 84901

Fax

+98 88633039

Email

drghasemim@yahoo.com ghasemi-

ma@razi.tums.ac.irghasemim841@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences,Obestetrics and Gynecology group ,infertility ward

Full name of responsible person

Dr Ashraf Alyacin

Position

professor of Obestetrics and Gynecology

Other areas of specialty/work

Street address

,Infertility ward ,Shariati Hospital ,Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 84901

Fax

+98 88633039

Email

ivfshariati69@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Ghasemi

Position

fellowship infertility

Other areas of specialty/work

Street address

Shariati Hospital , Jalal-Al-Ahmad BLV intersection Kargar shomali,Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 84901

Fax

+98 88633039

Email

drghasemim@yahoo.com
ghasemi-ma@razi.tums.ac.ir
ghasemim841@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