Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

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

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Email address

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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

emprovement 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
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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