Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Comparison of ovarian response to ovulation induction after laparoscopic cystectomy or medical management among infertile women with endometrioma undergoing assisted reproductive technology

Protocol summary

Summary

The purpose of this study is to compare the ovarian response to ovulation induction after laparoscopic cystectomy or medical management among infertile women suffering from endometrioma going through assisted reproductive technology. Our main objective is to define the exact number of oocytes retrieved after these two processes. The sample includes all infertile women aged 40 years or less, with asymptomatic endometrioma undergoing assisted reproductive technology. Diagnosis of endometrioma is based on the evidence found through trans vaginal ultrasound indicating round shaped homogeneous hypoechoe tissue. Infertile couples with maternal cause who undergo TESE (Testicular Sperm Extraction) or PESA (Percutaneous Epididimal Sperm Aspiration) are excluded from the current study. The sample includes 80 patients divided in two groups. First group involves patients with asymptomatic endometrioma receiving IM Dipherelin prior to ovulation induction and the second group are the patients undergoing ovulation induction after laparoscopic ovarian cystectomy followed by IM Dipherelin injection. All patients in both groups receive a single IM dose of Dipherelin monthly for 3 consecutive months before the start of ovulation induction by Gonadotropins. After observing at least two 18 mm follicles in trans vaginal ultrasound, 10 000 units, hCG (10000 units, IM) is injected. The following step is ovarian puncture guided by trans vaginal ultrasound under general anesthesia 36 hours later. Trans cervical embryo transfer is performed 3 days after the puncture. In this study, the following outcomes are compared between two groups: number of retrieved oocytes, dominant follicles, embryos; quality of embryos; the rate of fertilization, chemical and clinical pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106116689N2**
Registration date: **2012-11-05, 1391/08/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-05, 1391/08/15

Registrant information

Name

Sedigheh Hosseinimousa

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-01-04, 1390/10/14

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of ovarian response to ovulation induction after laparoscopic cystectomy or medical management among infertile women with endometrioma undergoing assisted reproductive technology

Public title
Treatment of endometrioma in infertile women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Infertile women with endometrioma requiring assisted reproductive technology Exclusion criteria: Age over 40 years; Endometrioma smaller than 2 cm or larger than 6 cm; Male infertility TESE (Testicular Sperm Extraction) or PESA (Percutaneous Epididimal Sperm Aspiration)
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
All volenteers with inclusion criteria are asked to participate in the current study if agreed, a informed consent form is signed. she is randomly assigned to one of two groups based in Bertoli distribution. If she has an objection, we will switch her to another group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tehran University of Medical Sciences
Street address
Ethic Committee, Tehran University of Medical Sciences, Poorsina Street, Tehran
City
Tehran
Postal code
Approval date
2012-01-02, 1390/10/12
Ethics committee reference number
90-02-30-14261-40996

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
ناباروري زنانه

2

Description of health condition studied
Endometriomas
ICD-10 code
N80.1
ICD-10 code description
اندومتريوزيزدرتخمدان

Primary outcomes

1

Description
The number of retrieved oocytes
Timepoint
84 days after the first Dipherelin injection
Method of measurement
Invert Microscope, Diaphot 300, Nikon, Japan

Secondary outcomes

1

Description
The number of dominant follicles
Timepoint
82 days after the first Dipherelin injection
Method of measurement
nGS= number of observed gestatinal sac in trans vaginal sonography, nET= number of embryonal transfer, clinical pregnancy rate(%)= nGS/ nET x100

2

Description
fertilization rate
Timepoint
87 days after the first Dipherelin injection
Method of measurement
nE= number of total embryos, nI= number of injected oocytes, fertilization rate(%)= nE/ nI x 100

3

Description
The number and quality of embryos
Timepoint
87 days after the first Dipherelin injection
Method of measurement
Invert Microscope, Diaphot 300, Nikon, Japan

4

Description
chemical pregnancy
Timepoint
101 days after the first Dipherelin injection
Method of measurement
βhCG test

5

Description
clinical pregnancy rate
Timepoint
115 days after the first Dipherelin injection
Method of measurement
nGS= number of observed gestatinal sac in trans vaginal sonography, nET= number of embryonal transfer, clinical pregnancy rate(%)= nGS/ nET x100

Intervention groups

1

Description
First group receives 3 consecutive single IM doses of Dipherelin 3.75mg (Beaufouipfen, France) in 3 consecutive months.Ten days after the third IM dose of Dipherelin ovarian stimulation is conducted by using Gonal F (Serono, Switzerland, 300-450IU daily), for one week. Then Gonal F is replaced by HMG (Ferring, Germany, 300-450IU daily) until the observation of 18mm follicles in trans vaginal ultrasound. For visualizing follicular development, trans vaginal ultrasound (Sonoline G20; Siemens Medical Solutions, California, USA) is performed every 4 days. After the observation of at least two 18mm follicles, HCG (Ferring Co, Germany, 10000IU, IM) is injected and after 36 hours oocyte retrieve is performed under general anesthesia. Three days after fertilization technique performed through intra cytoplasmic sperm injection (ICSI), trans cervical embryo transfer will be carried out. Detection of pregnancy is through serum BhCG analysis, 3 days after embryonic transfer and the clinical pregnancy is detected by the aid of trans vaginal ultrasound, two weeks later when the pregnancy sac is detected. Main outcome is the number of oocytes retrieved. The number of oocytes retrieved, dominant follicles, embryos; quality of embryos;the rate of fertilization, laboratory and clinical pregnancy are compared between two groups.
Category
Treatment - Drugs

2

Description
Second group receives 3 consecutive single IM doses of Dipherelin 3.75mg (Beaufouipfen, France) in 3 consecutive months after laparoscopic ovarian cystectomy. Ten days after the third IM dose of Dipherelin ovarian stimulation is conducted by using Gonal F (Serono, Switzerland, 300-450IU daily), for one week. Then Gonal F is replaced by HMG (Ferring, Germany, 300-450IU daily) until the observation of 18mm follicles in trans vaginal ultrasound. For visualizing follicular development, trans vaginal ultrasound (Sonoline G20, Siemens Medical Solutions, California, USA) is performed every 4 days. After observing at least two 18mm follicles, HCG (Ferring Co, Germany, 10000IU, IM) is injected and after 36 hours oocyte retrieve is performed under general anesthesia. Three days after fertilization technique performed through intra cytoplasmic sperm injection (ICSI), trans cervical embryo transfer is carried out. Detection of pregnancy is through serum BhCG analysis, 3 days after embryonic transfer and the clinical pregnancy is detected by the aid of trans vaginal ultrasound, two weeks later when the pregnancy sac is detected. Main outcome is the number of oocytes retrieved. The number of oocytes retrieved, dominant follicles, embryos; quality of embryos;the rate of fertilization, laboratory and clinical pregnancy are compared between two groups.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Unit, Shariati Hospital
Full name of responsible person
Dr Sedighe Hoseinimosa
Street address
Department of Infertility, Shariati Hospital, Tehran University of Medical Sciences, North Karegar Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotouhi
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Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, 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
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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