

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluating the Effects of Iatrogenic Endometrial Injury before Performing Intrauterine Insemination in Increasing Fertility in Couples Referred to infertility center

Protocol summary

Summary

In this study we investigated the effect of local endometrial injury on outcome on IUI cycles. This is a randomized clinical trial being performed at Shiraz Ghadir hospital and private infertility clinics during a 17-months period from January 2011 to May 2012. 144 women with unexplained, mild male factor and mild endometriosis selected for IUI cycles undergoing IUI. Patients were randomly (based on a computer random digit generator using their registration number) assigned to two groups. Group A underwent endometrial biopsy, by a Novak current biopsy catheter (Neuilly-en-Thelle, France) between days 6–8 of previous menstrual cycle before IUI (n=72) and group B (n=72) underwent IUI cycles without undergoing endometrial biopsy. All the patients received 100-mg per day clomiphene citrate (Razak Drug Laboratory, Tehran, Iran) for 5 days from the 5th to the 9th day of cycle and highly purified recombinant FSH (Gonal-f, Serono, Hellas, Puregon, Greece) was injected intramuscularly in a dosage of 100 unit/day from the 8th day of the cycle. Then 10000 units of human chorionic gonadotropin (hCG) (Choriomon, IBSA, Switzerland) was injected intramuscularly, if at least one dominant follicles with size of >18mm were seen by transvaginal sonography and serum E2 level was below 2000pg/ml. Intrauterine insemination (IUI) was performed after 36 hours hCG injection. Main outcomes included pregnancy rate, pregnancy rate per cycle, abortion and ongoing pregnancy rates and endometrial thickness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070810210N1**
Registration date: **2013-01-12, 1391/10/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-12, 1391/10/23

Registrant information

Name

Afsun Zarei

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1233 2365

Email address

zareia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research; Shiraz University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effects of Iatrogenic Endometrial Injury before Performing Intrauterine Insemination in Increasing

Fertility in Couples Referred to infertility center

Public title

Evaluating the Effects of Iatrogenic Endometrial Injury before Performing Intrauterine insemination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18–40 years old patients who suffered from unexplained infertility, mild male factor and mild endometriosis; All women had normal plasma concentrations of day 3 LH and FSH; normal tests of renal and hepatic function; normal complete blood counts; normal HSG, laparoscopy and hysteroscopy and negative pregnancy tests. When the endometriosis was diagnosed, the stage was determined according to the revised American society for reproductive medicine classification and the score was recorded. Only those with mild endometriosis were included in the study while those with moderate to severe endometriosis were excluded from the study. Exclusion criteria: hirsutism; autoimmune disorders; endocrinopathies; cirrhosis and other chronic liver diseases; cigarette smoker and/or alcohol abuser (each of the partner); ovarian hyperstimulation syndrome (OHSS); no desire to continue the program.

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: **144**

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

Ethics committee of Shiraz University of Medical Sciences

Street address

8th Floor, main building of Shiraz University of

Medical Sciences, Zand Avenue

City

Shiraz

Postal code

Iran

Approval date

2011-12-03, 1390/09/12

Ethics committee reference number

39731/04/9/ص/90/پ

Health conditions studied

1

Description of health condition studied

Infertility and treatment methods

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Pregnancy

Timepoint

two weeks after the missed period

Method of measurement

measuring level of blood BhCG by ELISA

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

4 weeks after the missed period

Method of measurement

detecting of intrauterine sac by vaginal sonography

Intervention groups

1

Description

Group A undergo endometrial biopsy, by a Novak current biopsy catheter (Neuilly-en-Thelle, France between days 6–8 of previous menstrual cycle before IUI (n=72) and group B (n=72) underwent IUI cycles without undergoing endometrial biopsy. All the patients received 100-mg per day clomiphene citrate (Razak Drug Laboratory, Tehran, Iran) for 5 days from the 5th to the 9th day of cycle and highly purified recombinant FSH (Gonal-f, Serono, Hellas, Puregon, Greece) was injected intramuscularly in a dosage of 100 unit/day from the 8th day of the cycle. Then 10000 units of human chorionic gonadotropin (hCG) (Choriomon, IBSA, Switzerland) was injected intramuscularly, if at least one dominant follicles with

size of >18mm were seen by transvaginal sonography and serum E2 level was below 2000pg/ml. Intrauterine insemination (IUI) was performed 36 hours after hCG injection .

Category

Treatment - Other

2

Description

In the control group no intervention will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center of Ghadir hospital

Full name of responsible person

Street address

Infertility Research Center, 4th Floor, Ghadir Hospital, Ghoran Avenue

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

8th Floor, main building of Shiraz University of Medical Sciences, Zand Avenue

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz university of medical sciences

Full name of responsible person

Dr. afsun Zarei

Position

Assistant professor of OB & GYN / Obstetrician and Gynecologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Infertility Research Center

Full name of responsible person

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Position

infertility fellowship

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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