Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

To compare the effect of endometrial local injury on frequency of pregnancy in couples with unexplained infertility by control group

Protocol summary

Summary

We will study the effect of induced endometrial local injury on endometrial receptivity and embryo implantation in unexplained infertile couples. This is a randomized clinical trial which will be conducted in Shiraz, Iran. Random selection to intervention and control group was performed by drawing a piece of paper from the bag containing equal number of folded printed paper for each group. Therefore, 234 unexplained infertile women are divided into two groups. Other inclusion criteria for female are aged 23 to 35 years old, body mass index between 18 and 25 (kg/m2), anti-mullerian hormone more than1 micro gram/Liter, follicle stimulating hormone levels less than 10 milli-International Unit/milli-liter on the third day of cycle, at least 10-12 follicles in AFC count and couples receiving no drugs for infertility at least for three previous months. Those (Each of the partner) who were cigarette smoker, and/or alcohol abuser will be excluded. All the patients will undergo optimal superovulation by clomiphene-citrate (Razac Drug Laboratory, Tehran, Iran) orally administered 100 milligram/day from day 3 to day 7 of the cycle and HMG-Merional (IBSA , Lugarno , Switzerland) intramuscularly administered 75 International Unit/day from the 6th to the 8th day. Endometrial local injury was performed in the posterior wall of the uterus by pipelle endometrial sampling(Pipelle de Cornier,Prodimed, Neuilly-en-Thelle, France) during pre-ovulatory days (the day of detecting urinary lutenizing hormone (LH)-surge) just in the case group. Then all the patients in both groups were instructed to follow a regularly timed intercourse. The pregnancy (positive blood Beta human chorionic gonadotropin test by ELISA) and clinical pregnancy (detection of intrauterine sac by vaginal sonography) will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012082510657N1**
Registration date: **2012-11-26, 1391/09/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-11-26, 1391/09/06

Registrant information

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Najmeh Maharlouei
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences, Infertility Research Center

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2012-03-01, 1390/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
To compare the effect of endometrial local injury on frequency of pregnancy in couples with unexplained infertility by control group

Public title
Effectiveness of uterine local injury in improving pregnancy in unexplained infertility

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1) Couples with no obvious reasons for infertility(normal routine infertility evaluation evaluation of infertility are normal) referring to Infertility Research Center in Shiraz, Iran were included in this study. 2) infertile women who were in their 23-35 years of age, 3) body mass index between 18 and 25 (kg/m2), 4)anti-mullerian hormone more than 1 µg/l ,5) follicle stimulating hormone levels less than 10 mIU/ml on the third day of cycle, 6) at least 10-12 follicles in AFC count and 7) couples receiving no drugs for infertility at least for three previous months . The exclusion criteria were 1) women younger than 23 or older than 35, as well as those (each of the infertile partner) who were cigarette smoker, and/or alcohol abuser.

Age
From **23 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **234**

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
713451978

Approval date
2012-10-02, 1391/07/11

Ethics committee reference number
CT-91-4816

Health conditions studied

1

Description of health condition studied
Infertility

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 Beta human chorionic gonadotropin 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
All the patients will undergo optimal superovulation by clomiphene-citrate (Razac Drug Laboratory,Tehran,Iran) orally administered 100 milligram/day from day 3 to day 7 of the cycle and HMG-Merional (IBSA , Lugarno , Switzerland) intramuscularly administered 75 International Unit/day from the 6th to the 8th day. just in the case group mild endometrial local injury was performed in the posterior fundal wall of the uterus by standard piplle endometrial sampling (Pipelle de Cornier, Prodimed, Neuilly-en-Thelle, France) during the preovulatory days (the day of detecting urinary lutenizing hormone (LH)-surge) . Then all the patients in both groups were instructed to follow a regularly timed

intercourse.

Category

Treatment - Other

2

Description

In the control group no intervention will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Research center

Full name of responsible person

Nasrin Dadras

Street address

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

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research; Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Ebrahim Parsanezhad

Street address

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

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Shiraz

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; 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

Health Policy Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Najmeh Maharlouei

Position

Assistant Professor

Other areas of specialty/work

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under training of 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