Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of NO donor with minimal stimulation on infertile patients with poly cystic ovarian syndrom in patient refer to Alzahea hospital

Protocol summary

Summary

In this study, 120 patients aged 20 to 35 years are suffering from PCO who refer to Al-Zahra Hospital, Tabriz, are examined; being open, one or both tubes In hysterosonography; husband's sperm analysis is suitable for IUI; infertility is more than 3 years. In case of adverse effects (headache is unbearable), the patient will be excluded. Patients were randomly divided into 2 groups of 60 people; in group 1, clomiphene 100 mg (drug manufacturing company, Iran) for 5 days from day 5 of the menstrual cycle with exogenous gonadotropins is given. In the study group2, vaginal nitric oxide tablets (ISMN) Twenty milligrams (drug manufacturing company, Iran) for 5 cycles until the day of ovulation (and pregnancy is diagnosed) is given . Transvaginal ultrasound every other day from day 12 to 18 cycles were carried out and to see Mature follicles and ovulation and endometrial thickness at the last ultrasound diagnosis is recorded. If you see at least an 18-mm follicle, injections five thousand units of HCG IM injections and IUI is done after 34 hours. Pregnancy can be determined by measuring serum BHCG. Treatment in each group continues for 3 cycles. The overall goal of this project is effects of NO donor with minimal stimulation on infertile patients with poly cystic ovarian syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011512146N1**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

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Recruitment status

Recruitment complete

Funding source
Vice chancellor for Research,Tabriz University Of Medical Sciences

Expected recruitment start date
2012-07-18, 1391/04/28
Expected recruitment end date
2013-06-23, 1392/04/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effects of NO donor with minimal stimulation on infertile patients with poly cystic ovarian syndrom in patient refer to Alzahea hospital

Public title

Effects of NO donor with minimal stimulation on infertile patients with poly cystic ovarian syndrom

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patient of PCO or in the age of 20 till 35 years old; in the histro salinography had open one or 2 tube and sperm analysis of husband suitable for IUI.
Exclusion criterion: incidence of adverse events(Unbearable headache).
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Ssciences, Golgasht avenue
City
Tabriz
Postal code
Approval date
2012-07-11, 1391/04/21
Ethics committee reference number
3697/4/5

Health conditions studied

1

Description of health condition studied
infertility in pco
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Pregnanacy
Timepoint
16 days after IUI
Method of measurement
serum B-hcG

Secondary outcomes

1

Description
Endometrial Thickness
Timepoint
every other day from day 12 to 18 mentural cycle
Method of measurement
Transvaginal Sonography

2

Description
Number of mature foliculs
Timepoint
every other day from day 12 to 18 mentural cycle
Method of measurement
Transvaginal sonography

Intervention groups

1

Description
Control group: 100mg Clomiphene during 5 days, that is started from fifth- day of menstrual period + Exogen gonadotropin
Category
Treatment - Drugs

2

Description
CISMN group: vaginal tablet from fifth day of menstrual have been given till diagnosis of prognancy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr.laaya Farzadi (Gynecologist)
Street address
, Alzahra hospital, Artesh jonoobi avenue
City

Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Ali Reza Ostad Rahimi
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
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,Tabriz 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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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