

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

Name

Laaya Farzadi

Name of organization / entity

Woman's Reproductive Health Research Center of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

farzadl@tbzmed.ac.ir

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 hysterosalpingography had open one or two tubes 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 Sciences, 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

Pregnancy

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 menstrual cycle

Method of measurement

Transvaginal Sonography

2

Description

Number of mature follicles

Timepoint

every other day from day 12 to 18 menstrual 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 + Exogenous gonadotropin

Category

Treatment - Drugs

2

Description

CISMN group: vaginal tablet from fifth day of menstrual period have been given till diagnosis of pregnancy

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

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

Tabriz University Of Medical Sciences

Full name of responsible person

Farzadi Laaya

Position

Fellowship of infertility

Other areas of specialty/work

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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