

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

compression of oral Dydrogestrone with vaginal Progesteron in IUI successfull in patient with unexplained infertility

Protocol summary

Study aim

Comparison effect of oral Dydrogestrone with vaginal progesterone on the success of intrauterine sperm injection in patients with unexplained infertility

Design

This study is a double blind randomized clinical trial study of Phase 3. Accidentally patients are divided between three groups with random allocation software. In this study.

Settings and conduct

This double blind clinical trial study will be conducted in 2021 and 2021 in Al-Shahid Beheshti hospital in Isfahan. In this study, 210 women with unexplained infertility were studied in 3 groups of 70 recipients receiving oral Dydrogestrone, vaginal Progesterone, and Placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria include women with unexplained infertility, indications for treatment of intrauterine sperm injection, maximum 45 years old and patient consent to participate in the study. Consumption of other interfering treatment regimens is also considered as a criterion for non-entry.

Intervention groups

Group 1: Patients undergoing intrauterine sperm injection with oral administration of Dydrogestrone oral tablets in the amount of 10 mg for 16 days
Group 2: Patients undergoing intrauterine sperm injection with 400 mg progesterone vaginal suppository, manufactured by Abureihan Iran Company, one overnight for 16 days
Group 3: Patients undergoing intrauterine sperm injection with oral medication for 16 days

Main outcome variables

Fertility success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N47**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **prospective**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

compression of oral Dydrogestrone with vaginal Progesteron in IUI successfull in patient with unexplained infertility

Public title

Comparison effect of oral dydrogesterone with vaginal progesterone in the treatment of infertility by intrauterine sperm injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Visiting women with unexplained infertility Indications for treatment of intrauterine sperm injection Patient's consent to participate in the study Maximum 45 years old

Exclusion criteria:

Do other infertility treatments at the same time

Age

To 45 years old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 210

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients in two groups is done using Random Allocation Software. In this software, first the total volume of the sample enters the software and in the next step, the number of groups is specified. Software output includes a list of numbers from 1 to 210 that are randomly distributed in groups A, B and C. Patients are divided into three groups according to the time list, according to the time list, so that the sample size reaches the required number.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of the type of medication they are taking. Diderotestron is marketed as the main drug and coded on the main drug and placebo, and is given to patients for use. The outcome of treatment is also checked by a gynecologist who is unaware of the type of medication being taken.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Research faculty, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8434193474

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.MUI.MED.REC.1397.337

Health conditions studied

1

Description of health condition studied

unexplained infertility

ICD-10 code

N97.9

ICD-10 code description

unexplained infertility

Primary outcomes

1

Description

Fertility success

Timepoint

16 days after treatment

Method of measurement

Measurement of beta HCG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Infertile women treated with intrauterine sperm injection with oral administration of 10 mg oral tablets of Dydrogesterone, one tablet per night for 16 days

Category

Treatment - Drugs

2

Description

Intervention Group 2: Infertile women treated with

intrauterine sperm injection with progesterone vaginal suppositories, 400 mg, one suppository per night for 16 days

Category

Treatment - Drugs

3

Description

Control group: Infertile women treated with intrauterine sperm injection with oral administration of didrogestrone placebo, one pill a night for 16 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Zeynab Navabi

Street address

Shahid Beheshti street, Motahari street, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hatav Ghasemi Tehrani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Province

Isfahan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to the government agency and it is not possible to publish its information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available