Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

compression of oral Dydrogestrone with vaginal Progestron 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 Dydrogesterone, 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)

Phone
+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 Progestron in IUI successfull in patient with unexplained infertility

Public title
Comparison effect of oral dydrogesterone with vaginalprogesterone 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 Medicla Sciences, Hezarjerib street, Isfahan
City
Isfahan
Province
Isfehan
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 didrogesterone 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

City

Isfahan

Province

Isfehan

Postal code

8434193474

Phone

+98 31 3668 5555

Email

dr.navabi88@gmaile.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Research faculty, Isfahan University of Medical Sciences, Hezarjerib street

City

Isfahan

Province

Isfehan

Postal code

8434193474

Phone

+98 31 3792 3060

Email

sh_haghjoo@med.mui.ac.ir

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

Street address

Shahid Beheshti hospital, Motahari street, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8434193474

Phone

+98 31 3668 5555

Email

tehrani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Shahid Beheshti hospital, Motahari street, Isfahan

City

Isfahan

Province

Isfehan

Postal code
8434193474
Phone
+98 31 3668 5555
Email
naghshineh@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ali Mehrabi Koushki
Position
Statistical Consultant
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Research faculty, school of medicine, Hezarjerib street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8434193474
Phone
+98 31 3792 8081
Email
al.mehrabi@gmail.com

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