

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of serum progesterone level on third day after intrauterine insemination on pregnancy outcomes in two routes of luteal phase support in women with unexplained infertility : A randomized clinical trial study.

Protocol summary

Study aim

Evaluation of serum progesterone level on third day after IUI on pregnancy outcomes in two methods of luteal phase support in women with unexplained infertility

Design

One-blind clinical trial with random assignment to the intervention group (receiving Crinone vaginal gel) and control (receiving Duphaston), the third phase of the trial on 70 infertile patients, randomization before the start of the study with Random allocation software function, IUI, assessment of pregnancy outcomes at the end of the study

Settings and conduct

On IUI day, all patients are randomly divided into two groups: intervention: receiving 90 mg / once daily vaginal crinone gel 8% , control group: receiving Duphaston 10 mg twice daily (oral form of progesterone) in all Patients continue to support the luteal phase until pregnancy testing, 14 days after IUI. Serum progesterone levels are measured in all patients 72 hours after IUI and pregnancy outcomes including biochemical pregnancy, clinical pregnancy, ongoing pregnancy, abortion in each patient are evaluated and the relationship between serum progesterone levels on the third day after IUI and these outcomes in each patient will be examined.

Participants/Inclusion and exclusion criteria

General admission requirements: Age range 18-37 IUI cycles Patients with normal uterine cavity Exclusion criteria: Patients with uterine problems such as fibroids; anatomical problems of the uterus, polyps; salpingitis Patients with a history of recurrent miscarriage RIF patients Age over 37 years Patients with grade 3 or 4 endometriosis Body mass index higher than 30 kg / m2 Patients with endometrial thickness less than 7 mm per day trigger

Intervention groups

A: receiving 90 mg / once daily vaginal crinone gel 8%)

B: receiving Duphaston 10 mg twice daily (oral form of progesterone)

Main outcome variables

Biochemical pregnancy, Clinical Pregnancy, abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048630N3**

Registration date: **2021-11-22, 1400/09/01**

Registration timing: **retrospective**

Last update: **2021-11-22, 1400/09/01**

Update count: **0**

Registration date

2021-11-22, 1400/09/01

Registrant information

Name

Ensieh Salehi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 76 3333 0755

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of serum progesterone level on third day after intrauterine insemination on pregnancy outcomes in two routes of luteal phase support in women with unexplained infertility : A randomized clinical trial study.

Public title

The effect of serum progesterone on third day after intrauterine insemination (IUI) on pregnancy outcomes in two different methods of progesterone administration

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

IUI cycles Patients with normal uterine cavity

Exclusion criteria:

Patients with uterine abnormalities such as myoma, anatomical problems, polyp, salpingitis Patients with a history of recurrent miscarriage Age over 37 years old Patients with grade 3 or 4 endometriosis BMI over 30 kg/m2 Previous ectopic pregnancy Usage two type of progesterone for luteal phase support Endometrial thickness lower than 7mm on trigger day

Age

From **18 years** old to **37 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly allocate the samples to each of the study groups, Random allocation software was used, which generated a random sequence using a single block method. The address of the software is as follows: <https://random-allocation-software.software.informer.com/2.0/>. How to randomize: This software according to the uniform statistical distribution of discrete sequence in the form of letters (or numerical) in the form of ... ABAABAABABBA produces that each letter belongs to a group to hide In order to hide the random allocation so that the assigned group is not known before the individual is assigned, each of the random sequences created is recorded on a card and the cards are placed in the envelopes , respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the

envelopes is opened in order and the assigned group of the participant is revealed. How to use the software by installing the software file and after opening it, first the number of groups is determined, then the sample size of each group and finally the method of numerical or letter randomization is selected in a simple or block form. In this study, the method A block was selected.

Blinding (investigator's opinion)

Single blinded

Blinding description

This research is a one-blind study. Thus, the person analyzing the results is unaware of the status of allocation in groups. R

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical board of Hormozgan University of Medical Sciences

Street address

Parastar Street

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Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.HUMS.REC.1400.100

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Biochemical pregnancy

Timepoint

14 days after IUI

Method of measurement

Beta serum level evaluation

2

Description

Biochemical pregnancy

Timepoint

8 weeks after IUI

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:receiving vaginal progesterone(crinone gel 8%), Crinone gel contains 90 mg of progesterone and is consumed once a day for 14 days.

Category

Treatment - Drugs

2

Description

Control group: receiving Progesterone in the form of Duphaston 10 mg tablets, for 14 days and twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center of Hormozgan University of Medical Sciences

Full name of responsible person

Dr.Maryam Azizi kuteanaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Maryam azizi kuteanaee

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data will be presented in the article after analysis

When the data will become available and for how long

2022

To whom data/document is available

Academic researchers and obstetricians

Under which criteria data/document could be used

Clinical application in patients undergoing IUI

From where data/document is obtainable

Paper corresponding author

What processes are involved for a request to access data/document

E-mail to corresponding author

Comments