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 aston 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

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Ensieh Salehi

Name of organization / entity

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Iran (Islamic Republic of)

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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, salpangitis 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
City
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 kutenaee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 kutenaee
Position
associate professor
Latest degree
Subspecialist
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Person responsible for updating data

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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