Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support in infertile women refereed to Infertility center affiliated to Hormozgan University of Medical Sciences : A randomized clinical trial study

Protocol summary

Study aim

Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support

Design

classification into two groups (IM group, Crinone group) 3 days before FET, freezed embryo transfer, evaluation of pregnancy outcomes

Settings and conduct

All infertile participants referred to the infertility center after obtaining informed consent involve the study and receive hormone therapy for preparing the endometrium for embryo transfer and subsequent rerceive luteal phase support. All patients are randomly divided into two groups before starting treatment: Group 1: Administration of 100 mg of progesterone as IM (two ampoules of 50 mg) from 3 days before embryo transfer until pregnancy test Group 2: Administration of 8% crinone gel (90 mg once daily) from 3 days before embryo transfer until pregnancy test In all patients, 2-3 good quality embryos are transferred 96 hours after the start of progesterone administration. Serum progesterone levels are measured 1 hour before embryo transfer and the pregnancy outcomes in each patient are assessed and the relationship between serum progesterone levels and these outcomes is assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Artificial endometrial preparing 18-37 years. ICSI/IVF cycles Having 2-3 high quality embryos Patients with normal uterine cavity Exclusion criteria: Patients with uterine problems Patients with a history of recurrent miscarriage RIF patients Age over 37 years Patients with grade 3 or 4 endometriosis Poor Embryo quality Ectopic pregnancy Patients with endometrial thickness less than 7 mm after hormone therapy

Intervention groups

Group1: women receiving progesterone IM Group2: women receiving vaginal progesterone (crinone gel 8%)

Main outcome variables

Biochemical pregnancy, clinical pregnancy, ongoing pregnancy, abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048630N2**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **prospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Ensieh Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 0755

Email address

salehiensieh@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-09-21, 1400/06/30
Expected recruitment end date
2021-11-21, 1400/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support in infertile women refereed to Infertility center affiliated to Hormozgan University of Medical Sciences : A randomized clinical trial study

Public title
Evaluation of serum progesterone level on the day of embryo transfer in frozen cycle at cleavage stage on pregnancy outcomes in two routes of luteal phase support in infertile women refereed to Infertility center affiliated to Hormozgan University of Medical Sciences : A randomized clinical trial study
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
ICSI/FET cycles Having 2-3 high quality embryo Patients with normal uterine cavity Infertile women between 18-37 years Artificial Endometrial preparing
Exclusion criteria:
RIF patients Aged over 37 years Patients with a history of recurrent miscarriage, implantation problem Patients with uterine abnormality like Fibroma, uterine anatomical problems, Polyp, intramural Myoma greater than 4 cm, salpangitis Patients with grade 3 or 4 endometriosis Body mass index higher than 30 kg / m2 Patients using two types of progesterone to support the luteal phase Patients with blastocyst transfer (fifth day embryo) Ectopic pregnancy Patients with endometrial thickness less than 7 mm after hormone therapy Poor quality embryo
Age
From **18 years** old to **37 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Eligible patients (including 100 patients) are randomly assigned by a statistical expert using a simple randomization method. In this method, the Random function between the Excell program is used to generate a random number between 1 and 2. This is repeated 100 times and thus a random sequence is obtained.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Imam Hossein Boulevard
City
Bandar abbas
Province
Hormozgan
Postal code
7919693116
Approval date
2021-08-10, 1400/05/19
Ethics committee reference number
IR.HUMS.REC.1400.192

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 FET
Method of measurement
beta serum level evaluation

2

Description
Clinical pregnancy
Timepoint
6 week after FET
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: receiving progesterone as IM
Category
Treatment - Drugs

2

Description
Intervention group 2: receiving vaginal progesterone(crinone gel 8%)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center affiliated to Hormozgan University of Medical Sciences
Full name of responsible person
Dr.Maryam Azizi kutenaee
Street address
Parastar Street
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3333 0755
Email
maryamazizikut86@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr.taymoor Aghamolaee
Street address
Imam Hossein Boulevard
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Phone
+98 76 3371 0393
Email
research@hums.ac.ir
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
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Parastar Street
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3333
Email
maryamazizikut86@gmail.com

Person responsible for scientific 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

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Parastar street

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Phone
+98 76 3333 0755

Email
maryamazizikut86@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dr. Ensieh Salehi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Biology

Street address
Parastar Street

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Phone
+98 76 3333 0755

Email
salehiensieh@gmail.com

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

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 Gynecologist

Under which criteria data/document could be used
Clinical application in patients undergoing ICSI/FET

From where data/document is obtainable
corresponding author

What processes are involved for a request to access data/document
E-mail to corresponding author

Comments