Influence of growth hormone supplementation on pregnancy outcome of patients undergoing frozen thawed embryo transfer (FET)

Protocol summary

Study aim
Influence of growth hormone supplementation on pregnancy outcome of frozen thawed embryo transfer cycle (FET)

Design
non randomized 2 arm parallel group with 50 patients

Settings and conduct
Endometrial preparation will be done from second day of cycle with 6mg daily estradiol in patient who are candidate for frozen thawed embryo transfer and serial sonography will be done from 12th day of cycle; when thickness reaches 7mm or more and patients have including criteria they will divided into 2 groups; in control group we just prescribe 400mg daily progesterone for 3 days and in case group they will receive 1.2 mg growth hormone along with 400mg progesterone. 72 hours later all patients will be transferred maximum 2 cleaved embryo; serum BHCG will be checked 2 weeks later and if it is positive, vaginal sonography must be done for identification of gestational sac with fetal heart beat.

Participants/inclusion and exclusion criteria
including criteria: 20-40 years old infertile patient who will transferred frozen thawed embryo and have adequate endometrial thickness excluding criteria: uterus malformation or adhesion, sever andometriosis or adenomyosis and recurrent implantation failure

Intervention groups
20-40 years old infertile woman who are candidate for frozen thawed embryo transfer and have appropriate endometrium received 1.2 mg daily growth hormone along with progesterone

Main outcome variables
chemical pregnancy; clinical pregnancy

General information
Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20091018002604N5
Registration date: 2020-03-02, 1398/12/12
Registration timing: retrospective

Last update: 2020-09-16, 1399/06/26
Update count: 1

Registration date
2020-03-02, 1398/12/12

Registrant information
Name
Robab Davar
Name of organization / entity
Yazd Research and Clinical Center for Infertility
Country
Iran (Islamic Republic of)
Phone
+98 35 1824 7085
Email address
davar@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-22, 1398/06/31
Expected recruitment end date
2020-02-03, 1398/11/14
Actual recruitment start date
2019-09-22, 1398/06/31
Actual recruitment end date
2020-02-03, 1398/11/14
Trial completion date
2020-03-04, 1398/12/14

Scientific title
Influence of growth hormone supplementation on pregnancy outcome of patients undergoing frozen thawed embryo transfer (FET)
Influence of adding growth hormone in frozen embryo transfer cycle outcome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
20-40 years old infertile patient candidate for frozen thawed embryo transfer
Exclusion criteria:
uterus malformation-sever endometriosis and adenomyosis-uterus adhesion-recurrent implantation failure

Age
From 20 years old to 40 years old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 100
Actual sample size reached: 100

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Research and Clinical Center for Infertility(Yazd Reproductive Sciences Institut
Street address
Research and Clinical Center for Infertility, BouAli avenue, Safaieye
City
Yazd
Province
Yazd
Postal code
8916777391
Approval date
2019-09-14, 1398/06/23
Ethics committee reference number
IR.SSU.RSI.REC.1398.025

Health conditions studied

1
Description of health condition studied
infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1
Description
chemical pregnancy
Timepoint
2weeks after embryo transfer
Method of measurement
serum BHCG

Secondary outcomes

1
Description
clinical pregnancy
Timepoint
2weeks after positive BHCG
Method of measurement
vaginal sonography

Intervention groups

1
Description
Intervention group: Endometriat preparation will be done for 20-40 years old infertile woman who are candidate for frozen thawed embryo transfer from second day of cycle with 6 mg daily estradiol and serial sonography will be done from 12th day of cycle ;when thickness reaches 7 mm ,they receive 1.2 mg daily growth hormone along with 400 mg progesterone for 3 days and then embryo transfer will be done.
Category
Treatment - Drugs

2
Description
Control group: : Endometriat preparation will be done for 20-40 years old infertile woman who are candidate for frozen thawed embryo transfer from second day of cycle with 6 mg daily estradiol and serial sonography will be done from 12th day of cycle ;when thickness reaches 7 mm ,they receive 400 mg progesterone for 3 days and then embryo transfer will be done.
Category
Treatment - Drugs
### Recruitment centers

1

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Research and Clinical Center for Infertility (Yazd Reproductive Sciences Institute)</th>
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<tbody>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Dr. Robab Davar</td>
<td></td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>Yazd, Safaeiyeh, Bouali ave.</td>
<td></td>
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<tr>
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<td><a href="mailto:info@yazd-rsi.ir">info@yazd-rsi.ir</a></td>
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<tr>
<td><strong>Web page address</strong></td>
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### Sponsors / Funding sources

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<table>
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<tr>
<th>Sponsor</th>
<th>Name of organization / entity</th>
<th>Vice chancellor for research, Shahid Sadoughi University of Medical Science, Yazd, Iran</th>
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<tbody>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Robab Davar</td>
<td></td>
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<tr>
<td><strong>Street address</strong></td>
<td>Safaeiyeh-Bouali ave-Research and Clinical Center for Infertility</td>
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### Person responsible for general inquiries

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<td><strong>Full name of responsible person</strong></td>
<td>Robab Davar M.D.</td>
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<td><strong>Position</strong></td>
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Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Yasamin Mehrolhasani
Position
Infertility Fellowship
Latest degree
Specialist
Other areas of specialty/work
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Phone
+98 35 3824 7085
Email
yasamin_m@yahoo.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
no more information exist
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