Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

assessment of the best luteal phase support (comparison of four protocols) for patients undergoing frozen-thawed embryo transfer in artificial cycle.

Protocol summary

Summary

overall objective of the best luteal phase support upon pregnancy outcome in frozen –thawed embryo transfer cycle dedicated objectives : 1-survey effect of didrogesteron in comparison by cyclogest upon clinical pregnancy rate in frozen thawed embryo transfer cycle 2- survey effect of didrogesteron in comparison by cyclogest upon ongoing pregnancy rate in frozen thawed embryo transfer cycle 3- survey effect of didrogesteron in comparison by cyclogest upon abortion rate in frozen –thawed embryo transfer cycle 4- survey effect of didrogesteron with GnRH-a in comparison by cyclogest upon clinical pregnancy rate in frozen –thawed embryo transfer cycle 5- survey effect of didrogesteron with GnRH-a in comparison by cyclogest upon ongoing pregnancy rate in frozen –thawed embryo transfer cycle 6-survey effect of didrogesteron with GnRH-a in comparison by cyclogest upon abortion rate in frozen –thawed embryo transfer cycle 7- survey effect of didrogesteron with HCG in comparison by cyclogest upon clinical pregnancy rate in frozen –thawed embryo transfer cycle 8-survey effect of didrogesteron with HCG in comparison by cyclogest upon ongoing pregnancy rate in frozen –thawed embryo transfer cycle 9- survey effect of didrogesteron with HCG in comparison by cyclogest upon abortion rate in frozen thawed embryo transfer cycle inclusion criteria: 1-unexplained infertility 2- tubal factor 3-mild male factor 4-POF 5-sub fertility in pco field 6-average age between 20-40 7-normal uterine cavity exclusion criteria: 1-women over 40 year 2-endometriosis stage III ،IV 3-Hydro salpinx 4- severe male factor 5-ab normal uterine cavity 6-failed embryo transfer cycle ≥3 methods: According to previous studies and consult with statistics 400 patients were entered to our study.patients who were scheduled for IVF in infertility clinic of mother and child hospital,and Dena hospital of Shiraz city were assessed for having inclusion criteria,patients that were 20-40 y with normal uterine cavity and special infertility cause were included and patients that had more than 40 y with abnormal uterine cavity and more or equal 3 unsuccessful embryo transfer cycle were excluded . After entrance to stimulation cycles ,in third day of past ovum pick up,embryos were assessed for quality and counts of blastomers.If number of blastomers were more than or equal 8 with fragmentation rate less than 20%,embryo was freezes as Top quality embryo with vitrification method in cleavage stage.The patients who had Top quality freeze embryo were admitted in next cycle for preparation endometrium. Estradiol was started from second day of menstrual cycle , progesterone ampule 100 mg/d for three days was prescribed after getting adequate endometrial thickness. Number of embryo for transfer was determined according to mother age. after taking testimonial form study,patients randomized and divided to four groups for receiving luteal phase support. - First group:patients who received cyclogest vaginal suppository 400 mg twice a day. - Second group: patients who received didrogesteron oral tablet 10 mg twice a day. - Third group: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp Dipherelin 0.1mg in days of embryo transfer,3 day,6 day . - Fourth group: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp HCG 1500u in days of embryo transfer,3 day,6 day - HCG Test was done 16 days after embryo transfer.if the test was positive ,trans vaginal ultra sound was done 6 week and 12 week later for determining clinical pregnancy rate and ongoing pregnancy rate.Meanwhile luteal phase support was continued till 12 week gestation. - Main outcome were consist of clinical pregnancy rate ,ongoing pregnancy rate, abortion rate that was recorded for 4 groups and after statistical analysis were compared for assessing best luteal phase support in frozen-thaw embryo transfer cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082510210N3**
Registration date: **2015-02-14, 1393/11/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-14, 1393/11/25

Registrant information

Name
Afsun Zarei
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1233 2365
Email address
zareia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Scienses

Expected recruitment start date

2014-12-16, 1393/09/25

Expected recruitment end date

2015-06-15, 1394/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

assessment of the best luteal phase support (comparison of four protocols) for patients undergoing frozen-thawed embryo transfer in artificial cycle.

Public title

Effect of four treatment protocols upon pregnancy outcome in frozen-thawed embryo transfer cycle.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: unexplained infertility ؛ tubal factor؛ mild male factor ؛ POF ؛ sub fertility in pco field ؛ average age between 20-40؛ normal uterine cavity exclusion criteria: women over 40 year؛ endometriosis stage III ،IV؛ Hydro salpinx ؛ severe male factor؛ ab normal uterine cavity ؛ failed embryo transfer cycle ≥3

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Science Researching، Shiraz Univercity of Medical Science
Street address
Shiraz University of Medical Sciences، Zand Street، Shiraz
City
Shiraz
Postal code

Approval date

2014-12-14, 1393/09/23

Ethics committee reference number

ct-p-9384-8114

Health conditions studied

1

Description of health condition studied

luteal phase

ICD-10 code

N94.8

ICD-10 code description

Other specified conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

6 week gestation

Method of measurement

vaginal sonogeraphy trans

Secondary outcomes

1

Description
ongoing pregnancy rate,Abortion rate
Timepoint
12 week gestation
Method of measurement
vaginal sonogeraphy trans

Intervention groups

1

Description
control group : received cyclogest vaginal suppository twice a day for luteal phase support
Category
Treatment - Drugs

2

Description
intervention group 1: patients who received didrogesteron oral tablet 10mg twice a day.
Category
Treatment - Drugs

3

Description
intervention group2: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp Dipherelin 0.1mg in days of embryo transfer,(3 day,6 day)
Category
Treatment - Drugs

4

Description
intervention group3: patients who received didrogesteron oral tablet 10mg twice a day in combination with 3 dose of Amp HCG 1500u in days of embryo transfer,(3 day,6 day)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mother & Child hospital
Full name of responsible person
Parastoo soheil
Street address
Shiraz University of Medical Sciences، Zand Street، Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
Street address
Shiraz University of Medical Sciences، Zand Street، Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr parastoo soheil
Position
Fellowship of Obstetrics & GYN, Infertility
Other areas of specialty/work
Street address
Shiraz university of medical science ، zand street
City
Shiraz
Postal code
Phone
+98 71 3227 9715
Fax
Email
Parastoosoheil@yahoo.com s.kharati@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Science

Full name of responsible person
Dr afsoon zarei

Position
Professor of Obstetrics & GYN, Fellowship Infertility

Other areas of specialty/work

Street address
Shiraz University of Medical Science , Zand Street

City
Shiraz

Postal code

Phone
+98 71 3227 9715

Fax

Email
zareia@sums.ac.ir s.kharati@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Science

Full name of responsible person
Sara kharati

Position

Other areas of specialty/work

Street address

City
Shiraz

Postal code

Phone
+98 917 801 5165

Fax

Email
s.kharati@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty