Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Prednisolone on pregnancy outcomes among infertile patients undergoing Intra Cytoplasmic Sperm Injection (ICSI)

Protocol summary

Summary

This study tried to show how corticosteroid therapy improves the results of ICSI. This semi clinical trial study) without control group (was included 248 infertile women were candidate to ICSI of Kosar infertility center in urmia university of medical sciences since 2011 to2013.Patiants were received Prednisolone that get started 20 mg/day from one day before embryo transfer to 7days then stopped. women were followed by pregnancy test (B-hCG), then in the 6 and 20 weeks by sonography. Incidence rate of Biochemical pregnancy, clinical pregnancy rate, incidence rate of abortion before appearance of fetal heart (6weeks), intra uterus pregnancy, incidence rate of abortion before 20weeks, Incidence rate of Ectopic pregnancy were compared between groups.

General information

Acronym

prednizolone and microinjection

IRCT registration information

IRCT registration number: **IRCT2014111213421N2**
Registration date: **2015-01-10, 1393/10/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-10, 1393/10/20

Registrant information

Name

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Name of organization / entity

Urmia University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Urmia University of Medical Sciences, Reproductive Health Reasearch Center

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Prednisolone on pregnancy outcomes among infertile patients undergoing Intra Cytoplasmic Sperm Injection (ICSI)

Public title

Prednisolone on pregnancy outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

i nclusion criteria: having infertility;FSH serum levels lower than 10 ,age of lower than 42 years exclusion criteria: having asthma; systemic disorders; gastrointestinal disorders

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **248**

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

Urmia University of Medical Sciences

Street address

Urmia, Urmia University of Medical Sciences

City

Urmia

Postal code

-

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

umsu.rec.1392.115

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

abortion

Timepoint

until 20 weeks

Method of measurement

observation

2

Description

intra uterus pregnancy

Timepoint

12,20 weeks

Method of measurement

sonography

3

Description

chemical pregnancy

Timepoint

6 weeks

Method of measurement

BHCG mesuring

Secondary outcomes

1

Description

none

Timepoint

none

Method of measurement

none

Intervention groups

1

Description

Control group: Patients who candidate for microinjection (ICSI), underwent for induction of ovulation, underwent by long protocol in the beginning of cycle. Determination of uterus depth was done for all patients. For all of patients were given 100 mg/12 hrs Doxycycline for 10 days and 1 mg daily Folic acid from the previous cycle, Contraceptive pills daily started on the second day of their menses and continued for 21 day. 50 line of insulin syringe Superfact (Buserelin) was injected sc. 6 days before menstruation. After end of 21 contraception pill consumption, on the second day of menstral cycle the injected dose of Superfact GnRH Antagonist (Buserelin) was reduced to half. First, we started gonadotropin (Gonal.F) S.C from second days, after 1 week , Gonal.F and menogone to given suitable follicles. Dose of gonadotropin was determined base on age, FSH level , amount of antral folicule and history of IVF. The size of the follicles and endometrial thickness was monitored by transvaginal sonography. Once at least 3 follicles reached the size of 18 mm, 10000 units hCG (FERRING-Germany) was injected to the patient. Ovum pick up was done 34 hours after the injection by transvaginal sonography under spinal or light general anesthesia were extracted. After 72 hours ,embryos were transferred in distance 1cm up to foundus of uterus. Same sequential media (GII series, VitrolifeTM ; Colorado, USA) was used for all embryo culturing. Embryo scoring was done according to zonal thickness, cytoplasm fragmentation,

blastomeres number, and morphology. The clinician also made sure that the endometrium has three lines and its thickness is 8-10 mm. for luteal phase support 100 mg progesterone IM daily were given from ovum pick up day , detecting receiving positive β HCG results and detecting of fetal heart by sonography , respectively to 11 weeks of pregnancy.

Category

Treatment - Drugs

2

Description

Intervention Group also followed the same procedure as control groups and the same medications were used. In addition, 20 mg daily prednisolone was given to all Intervention Group, One day before the emberyo transfer, 20 mg daily prednisolone were used for one week. Prednisolone’s dose reduced to 10 mg daily for the second week and 5 mg daily in the last 2 days and then was stopped. One tablet Ranitidine also was used to prevent any possible stomach and intestinal discomfort in the morning.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Genecology Center

Full name of responsible person

Fariba Nanbakhsh

Street address

Urmia , Kashani Street , Motahari Hospital

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

shamsimirigafarzadeh

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Urmia , Djahad Avenue,PO BOX 1138, Urmia.Iran

City

Urmia

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urmia 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

Reproductive Health Research Center

Full name of responsible person

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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