

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of calcium ionophore on fertilization and pregnancy rate in infertile patients with teratospermia candidate for Intracytoplasmic sperm injection

Protocol summary

Summary

The aim of this prospective randomized controlled study is evaluating the effect calcium ionophore on fertilization and pregnancy rate in infertile men suffer teratospermia . Inclusion criteria: Teratospermic men with normal morphology less than 14%, who are candidate for Intracytoplasmic sperm injection Exclusion criteria: women older than 40 years; women with FSH higher than 12; immature oocytes Three hundred oocyte (150 each group) from womem with teratospermic partner, who are candidate for Intracytoplasmic sperm injection will be chosed from April till March 2012. In control group usual Intracytoplasmic sperm injection will be performed. In intervention group after oocytes retrieval, they will be entered to culture media plus 5 mic/ml calcium ionophore for 5 minutes, and then will be washed at least 5 time by mops solution .After 16-18 hours they will be evaluated for fertilization. Primary outcomes: Fertilization rate, Chemical pregnancy, Chemical pregnancy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012112610328N1**

Registration date: **2012-11-26, 1391/09/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-26, 1391/09/06

Registrant information

Name

Sima Janati

Name of organization / entity

Research and Clinical Center for Infertility, Dezful
University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences Yazd

Expected recruitment start date

2012-04-02, 1391/01/14

Expected recruitment end date

2013-03-18, 1391/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of calcium ionophore on fertilization and pregnancy rate in infertile patients with teratospermia candidate for Intracytoplasmic sperm injection

Public title

Effect of calcium ionophore on oocyte activation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Teratospermic men with normal morphology less than 14%,who are candidate for Intracytoplasmic sperm injection Exclusion criteria:women older than 40 years;women with FSH

higher than 12; immature oocytes

Age

From **18 years** old to **39 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

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

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bouali Ave, Safayeh, Research and Clinical Center for Infertility, Yazd

City

Yazd

Postal code

Approval date

2012-03-15, 1390/12/25

Ethics committee reference number

3770

Health conditions studied

1

Description of health condition studied

Male Infertility

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

Fertilization rate

Timepoint

16-18 hours

Method of measurement

Observation with microscope

2

Description

Clinical pregnancy

Timepoint

2-3 weeks after positive B-hCG

Method of measurement

Observation of fetal heart activity by transvaginal ultrasonography

3

Description

Chemical pregnancy

Timepoint

After 14 days of embryo transfer

Method of measurement

Measurement of serum B-hCG

Secondary outcomes

1

Description

Cell division

Timepoint

Two days

Method of measurement

Observation with microscope

2

Description

Embryo quality

Timepoint

Two days

Method of measurement

Observation by microscope according to the symmetric and exact of Blastomer pieces

Intervention groups

1

Description

In intervention group (n=150 oocyte) after oocytes retrieval, they will be entered to culture media plus 5 mic/ml calcium ionophore for 5 minutes, and then will be washed at least 5 time by mops solution .After 16-18 hours they will be evaluated for fertilization. Primary outcomes: Fertilization rate, Chemical pregnancy, Chemical pregnancy

Category

Treatment - Drugs

2

Description

In control(n=150 oocyte) group usual Intracytoplasmic sperm injection will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Science ,Yazd

Full name of responsible person

Dr. Maryam Eftekhar

Street address

Boali Ave, Safayeh , Research and Clinical Center for Infertility,Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vise Chancellor of Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Dr. Maryam Eftekhar

Street address

Bouali Ave, Safayeh, Research and Clinical Center for Infertility, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vise Chancellor of Shahid Sadoughi University of Medical Sciences, Yazd

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

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Dr. Sima Janati

Position

Assisted professor of Obstetrics and Gynecology, fellowship of infertility in state of training

Other areas of specialty/work

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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