

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of effect of calcium ionophore on oocyte activation in infertile patient with normal sperm morphology and low fertilization after microinjection

Protocol summary

Summary

The aim of this prospective randomized controlled study is evaluating the effect calcium ionophore on fertilization and pregnancy rate in patients with history of fertilization rate less than 50% in previous micro injection cycle and normal sperm morphology who are candidate for Intracytoplasmic sperm injection Exclusion criteria: women older than 40 years; women with FSH higher than 12; history of endocrine disorder. 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, secondary outcomes: Chemical pregnancy, Clinical pregnancy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501266420N12**
Registration date: **2015-10-20, 1394/07/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-20, 1394/07/28

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of calcium ionophore on oocyte activation in infertile patient with normal sperm morphology and low fertilization after microinjection

Public title

Effect of adding calcium ionophore on medium of oocyte

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with history of fertilization less than 50% in previous micro injection cycle, who are candidate for Intracytoplasmic sperm injection and morphology of sperm is normal. Exclusion criteria: women older than 40 years; women with FSH higher than 12; history of endocrine disorder

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 80

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**

Ethics committee of Shahid Sadoughi University of Medical Science

Street address

Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd

City

YAZD

Postal code

8916877391

Approval date

2015-08-02, 1394/05/11

Ethics committee reference number

IR.SSU.RSI.REC.1394.3

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes**1****Description**

fertilization rat

Timepoint

16-18 hour

Method of measurement

Observation with microscope

Secondary outcomes**1****Description**

chemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

serum β hCG

2**Description**

clinical pregnancy

Timepoint

3 weeks after positive serum β hCG

Method of measurement

vaginal ultrosonography

Intervention groups**1****Description**

in intervention group 5 mmol/ml calcium ionophore in medium culture, immediately after ICSI, for 5 minutes and then washed at least 5 time by mops solution.

Category

Treatment - Drugs

2**Description**

In control 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

Full name of responsible person

Dr.Maryam Eftekhari, Associated Professor of Shahid Sadoughi University of medical science

Street address

Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Sadoughi
University of Medical Sciences

Full name of responsible person

Dr.Abass Aflatounian

Street address

Research and Clinical Center for Infertility, Bouali,
Timsar Fallahy, Safayeh, Yazd

City

Yazd

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 Shahid Sadoughi
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**

Sadoughi University of Medical Science ,Yazd

Full name of responsible person

Maryam Eftekhari

Position

Associated Professor

Other areas of specialty/work**Street address**

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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