Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 βhCG

2

Description
clinical pregnancy
Timepoint
3 weeks after positive serum βhCG
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 Eftekhar, 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
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Person responsible for updating data

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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