

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Clinical Outcomes of Activated Oocyte with Ionomycin and Strontium Chloride in Intra Cytoplasmic Sperm Injection Candidates

Protocol summary

Summary

Objectives: Comparison of the effect of strontium chloride with calcium ionophore (Ionomycin) on intra cytoplasmic sperm injection (ICSI) clinical outcomes. Design: 105 couple's candidate of ICSI and artificial oocyte activation (AOA) with male factor infertility that referred to the Isfahan Fertility and Infertility Center (IFIC), are included in this study. All of the patients provided written informed consent and counseled regarding the AOA procedure and type of chemicals (ionomycin and strontium chloride). Based on treatment procedure, this single - blind clinical trial is designed that embryologist, is blinded regarding the groups and type of chemical stimuli used for AOA. Intervention: In "study group", injected oocytes from each couples are randomly divided into two groups, one group are activated with 10 μ M Ionomycin and the oocytes in the other group, activated with 10 mM strontium chloride. In "external control group", all of the injected oocytes were artificially activated by exposure to 10 μ M Ionomycin. Major Inclusion and Exclusion criteria: Inclusion criteria: Infertile couples with male factor etiology showing 99-100 % abnormal sperm morphology Exclusion criteria: Females with higher than 45, with less than 6 matured oocytes, immature, deformed. Main outcome measures (variables): This is the first clinical trial that are designed to compare the effect of strontium chloride with calcium ionosphere on ICSI clinical outcomes for example fertilization rate, embryo quality and pregnancy rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510257223N7**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Mohammad Hossein Nasr-Esfahani

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

Country

Iran (Islamic Republic of)

Phone

+98 31 9501 5688

Email address

mh_nasr@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Royan Institute, Dr. Abdolhossein Shahverdi Address: Hafez St, Banihashem Ave, Resalat Highway, Tehran, Iran, Royan Institute Telephone: 00982123562674

Expected recruitment start date

2014-09-25, 1393/07/03

Expected recruitment end date

2015-12-11, 1394/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Clinical Outcomes of Activated Oocyte with Ionomycin and Strontium Chloride in Intra Cytoplasmic Sperm Injection Candidates

Public title

Evaluation of Clinical Outcomes of Artificial Oocyte Activation in Intra Cytoplasmic Sperm Injection Candidates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertile couples with male factor etiology showing 99-100 % abnormal sperm morphology
Exclusion Criteria: Females with higher than 45, with less than 6 matured oocytes, immature, deformed.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **105**

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

Ethic Committee of Royan Institute

Street address

Hafez St, Banihashem Ave, Resalat Highway, Tehran, Iran, Royan Institute

City

Tehran

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

EC/93/1104

Health conditions studied

1

Description of health condition studied

Male factor infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm concentration

Timepoint

In daye of ICSI procedure

Method of measurement

Light microscopy according to (WHO, 2010) criteria

2

Description

Sperm motility

Timepoint

In daye of ICSI procedure

Method of measurement

Light microscopy according to (WHO, 2010) criteria

3

Description

Sperm morphology

Timepoint

In daye of ICSI procedure

Method of measurement

Light microscopy according to (WHO, 2010) criteria

4

Description

Fertilization rate

Timepoint

16 - 20 h after injection

Method of measurement

View of two pronuclei with invert microscope

5

Description

Quality of embryo

Timepoint

Three days after injection

Method of measurement

Using a three-point scoring system including fragmentation rate, number of blastomere, shape and size

6

Description

Chemical pregnancy

Timepoint

14 days after ET (Embryo Transfer)

Method of measurement

Measurement of quantitative serum β -hCG

7

Description

Clinical pregnancy

Timepoint

5 - 6 weeks following ET

Method of measurement

Ultrasound detection of an intrauterine gestational sac with a positive fetal heartbeat

Secondary outcomes

empty

Intervention groups

1

Description

Intervention or study group: Sibling oocytes are split into two groups: one group are artificially activated with 10 mM strontium chloride in GPGD medium (Calcium- and Magnesium-free MOPS buffered), 30 minutes post-ICSI, for 60 minutes.

Category

Other

2

Description

Internal control group: The oocytes in the other group, are activated 10 µM Ionomycin immediately after ICSI in G1 medium for 10 minutes

Category

Other

3

Description

External control group: The injected oocytes are artificially activated with 10 µM Ionomycin in G1 medium for 10 minutes immediately post-ICSI.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Fertility and Infertility Center

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Street address

Salman Farsi St, Isfahan, Iran, Fertility and Infertility Center

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Vice Chancellor for Research of Royan Institute, Dr. Abdolhossein Shahverdi

Street address

Hafez St, Banihashem Ave, Resalat Highway, Tehran, Iran, Royan Institute

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

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

Royan Institute (Royan Institute for Biotechnology)

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor, Head of Royan Institute for Biotechnology

Other areas of specialty/work

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Person responsible for scientific inquiries

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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

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

Full name of responsible person

Mohammad Hossein Nasr-Esfahani

Position

Professor, Head of Royan Institute for Biotechnology

Other areas of specialty/work