

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the effect of using or not using of artificial oocyte activation on intra-Cytoplasmic sperm injection outcomes in infertile patients with phospholipase C ζ deficiency

Protocol summary

Study aim

Comparison of the effect of using or not using of artificial oocyte activation on intra-Cytoplasmic sperm injection outcomes in infertile patients with phospholipase C ζ deficiency

Design

In this study, PLC ζ will be used as a diagnostic biomarker in couples subjected to intra-cytoplasmic sperm injection (ICSI). The oocytes obtained from patients who are deficient in this protein, will be randomly divided into two parts following the ICSI method. Assisted oocyte activation (AOA) will be used for one part of oocytes (group treatment, n=110), while the other part will not be received AOA (control group, n=110). Finally, the effect of AOA on fertilization rate, embryo cleavage, and embryo quality will be evaluated in preimplantation embryos microscopically and will be compared between groups.

Settings and conduct

Semen samples from infertile men referred to infertility clinic of Taleghani hospital will be assessed by PLC ζ immunofluorescence staining.

Participants/Inclusion and exclusion criteria

By evaluating PLC ζ , measured by immunofluorescence staining, semen samples with PLC ζ deficiency will be determined and entered to the study.

Intervention groups

1- Group treatment: one part of oocytes that will receive assisted oocyte activation (AOA). 1- Group control: other part of oocytes that will not receive AOA.

Main outcome variables

The comparison of fertilization rate, embryo cleavage, and embryo quality in preimplantation stage in infertile patients with PLC ζ deficiency in studied groups

General information

Reason for update

Acronym

AOA

IRCT registration information

IRCT registration number: **IRCT20160722029027N4**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

nazari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of using or not using of artificial oocyte activation on intra-Cytoplasmic sperm injection outcomes in infertile patients with phospholipase C ζ deficiency

Public title

Effect of artificial oocyte activation on intra-Cytoplasmic sperm injection outcomes in specific infertile patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

couples subjected to ICSI cycles male factor infertility

Exclusion criteria:

any history of trauma and surgery in the testis age >40 years in men any female factor infertility such as endometriosis and poly cystic ovarian syndrome (PCOs) age >35 years in women

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In the study, the oocytes derived from each couple in the ICSI cycle are randomly divided into two groups of control and treatment.

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 Beheshti University

Street address

Shahid chamran highway, Evin, next to Taleghani hospital

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.SBMU.MSP.REC.1395.93.

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

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

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

Fertilization rate

Timepoint

3 days

Method of measurement

obsrevation with loop microscope

2**Description**

embryo cleavage

Timepoint

3 days

Method of measurement

obsrevation with loop microscope

3**Description**

embryo quality

Timepoint

3 days

Method of measurement

obsrevation with loop microscope

Secondary outcomes

empty

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

Intervention= exposing oocytes in calcium ionophore A23187 following ICSI for 10 min and 10mM (sigma-aldrich). A23187 facilitate passing Ca ions from oocyte's membrane.

Category

N/A

2

Description

Control= putting oocytes in culture medium following ICSI without calcium ionophore. The procedure is similar to conventional ICSI cycles.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility and IVF ward of Talghani hospital

Full name of responsible person

Dr. Leila Nazari

Street address

Yaman St, Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

nazari@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences,
Yaman st, Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nahid Azad

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Shahid Beheshti University of Medical Sciences,
Yaman st, Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

193954719

Phone

+98 21 2387 2555

Fax

Email

nazad1390@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Nazari

Position

Fellowship of Infertility

Latest degree

Specialist

Other areas of specialty/work

infertility

Street address

Yaman St, Velenjak, Chamran highway, Infertility and

IVF ward of Talghani hospital

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2558

Fax

Email

nazari@sbmu.ac.ir

Web page address

Email

nazad1390@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure will be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

increasing the clinical information and for review articles

From where data/document is obtainable

via email address: nazad1390@gmail.com

What processes are involved for a request to access data/document

Access will be done with the opinion of the professors involved in the work

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nahid Azad

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Shahid Beheshti University of Medical Sciences,
Yaman st, Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1655133931

Phone

+98 21 2387 2555

Fax