

# 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 $\zeta$ 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  $\zeta$  deficiency

##### Design

In this study, PLC $\zeta$  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 $\zeta$  immunofluorescence staining.

##### Participants/Inclusion and exclusion criteria

By evaluating PLC $\zeta$ , measured by immunofluorescence staining, semen samples with PLC $\zeta$  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 $\zeta$  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  $\zeta$  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**