

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

**To investigate the efficacy of mesenchymal stem cell conditioned media (MSCs-CM) on modulate apoptotic and stress-related gene expression, ameliorate maturation and developmental potential of immature human oocytes after artificial activation in the infertile female.**

### Protocol summary

#### Summary

Objective: To investigate the efficacy of mesenchymal stem cell conditioned media (MSCs-CM) on modulate apoptotic and stress-related gene expression, ameliorate maturation and developmental potential of immature human oocytes after artificial activation in the infertile female. Study design: experimental, randomized clinical trial. Inclusion criteria: the age below 35 years old. Exclusion criteria: endometriosis; poly cystic ovarian syndrome; abnormal chromosome; low ovarian response; chronic anovulation and fewer than five oocytes in retrieval. Method: 200 germinal vesicle (GV) oocytes from 100 patients who experienced an ICSI (Intracytoplasmic sperm injection) cycle randomly divided into 4 gropes, Intervention group 1:50 germinal vesicles will be used in  $\alpha$ -minimal essential medium ( $\alpha$ -MEM) and then into fresh (fIVM). Intervention group 2: 50 germinal vesicles will be used in  $\alpha$ -minimal essential medium ( $\alpha$ -MEM) and then into vitrification (vIVM). Control group 1: 50 germinal vesicles will be used in MSCs-CM derived human umbilical cord and then into fresh (fIVM). Control group 2: 50 germinal vesicles will be used in MSCs-CM derived human umbilical cord and then into vitrification (vIVM). The expression of the BCL2, BAX, SOD and HSP70 genes will evaluate by Quantitative RT-PCR in IVM groups after oocytes maturation, which will be compared with control fresh and vitrified in-vivo maturity oocytes by stereo microscope for all four groups. The developmental competence was evaluated after artificial activation by ionomycin 24 and 48 hours after insertion in the medium.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2017101736840N1**

Registration date: **2017-11-11, 1396/08/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2017-11-11, 1396/08/20

#### Registrant information

##### Name

Hakimeh Akbari

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3322 1662

##### Email address

ghsuper@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice Chancellor for Research, Kerman University of Medical Sciences

#### Expected recruitment start date

2015-04-01, 1394/01/12

#### Expected recruitment end date

2016-04-01, 1395/01/13

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

To investigate the efficacy of mesenchymal stem cell conditioned media (MSCs-CM) on modulate apoptotic and stress-related gene expression, ameliorate maturation and developmental potential of immature human oocytes after artificial activation in the infertile female.

## Public title

To investigate the efficacy of mesenchymal stem cell conditioned media (MSCs-CM) on ameliorate maturation and developmental potential of immature human oocytes after artificial activation in the infertile female.

## Purpose

Basic science

## Inclusion/Exclusion criteria

Inclusion criteria: the age lower than 35 years old.

Exclusion criteria: endometriosis; polycystic ovarian syndrome; abnormal chromosome; low ovarian response; chronic anovulation and fewer than five oocytes on retrieval.

## Age

To 35 years old

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 100

## Randomization (investigator's opinion)

N/A

## 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 Kerman University of Medical Sciences

##### Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Kerman University of Medical Sciences, street

##### City

Kerman

##### Postal code

##### Approval date

2014-09-23, 1393/07/01

## Ethics committee reference number

IR.KUM.REC.1393.692

## Health conditions studied

### 1

#### Description of health condition studied

Female infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Expression of the BCL2, BAX, SOD and HSP70 genes

#### Timepoint

after oocytes maturation

#### Method of measurement

by Quantitative RT-PCR

## Secondary outcomes

### 1

#### Description

maturity of oocytes

#### Timepoint

24 and 48 hours after insertion in the medium

#### Method of measurement

by stereo microscope

### 2

#### Description

developmental competence

#### Timepoint

24 and 48 hours after insertion in the medium

#### Method of measurement

ionomycin

## Intervention groups

### 1

#### Description

Intervention group 1: 50 germinal vesicles will be used in  $\alpha$ -minimal essential medium ( $\alpha$ -MEM) and then randomly be into fresh (fIVM).

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: 50 germinal vesicles will be used in

$\alpha$ -minimal essential medium ( $\alpha$ -MEM) and then randomly be into vitrification (vIVM).

#### Category

Treatment - Drugs

### 3

#### Description

Control group 1: 50 germinal vesicles will be used in MSCs-CM derived human umbilical cord and then randomly be into fresh (fIVM).

#### Category

Treatment - Drugs

### 4

#### Description

Control group 2: 50 germinal vesicles will be used in MSCs-CM derived human umbilical cord and then randomly be into vitrification (vIVM).

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Afzalipour Infertility Center

##### Full name of responsible person

Hakime Akbari

##### Street address

next to Shahid Bahonar University, Imam Highway

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Kerman University of Medical Sciences

##### Full name of responsible person

Abbass Pardakhti

##### Street address

Beginning along the path of the seven Gardens of Olavi., Kerman University of Medical Sciences

##### City

Kerman

#### Grant name

این پروتکل در طرحی با نام " بررسی اثر محیط های پالایش شده بر فراساختار، تغییرات سلولی و مولکولی بلوغ تخمک های نابالغ انسانی منجمد شده به روش شیشه ای " ثبت و تایید اخلاقی دریافت کرده است

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for Research, Kerman 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

Kerman University of Medical Sciences

##### Full name of responsible person

Hakime Akbari

##### Position

PhD in Anatomy

##### Other areas of specialty/work

##### Street address

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Kerman

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##### Phone

+98 34 3132 5700

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ghsuper@sums.ac.it

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Seyed Hasan Eftekhari Vaghefi

##### Position

PhD in Anatomy

##### Other areas of specialty/work

##### Street address

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sheftekhari@yahoo.com

##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Masihi

**Position**

MS in english teaching ,BS in anesthesia/English  
Consultant

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

5th floor, Mohammad Rasul Allah Research Tower,  
Khalili Street

**City**

Shiraz

**Postal code****Phone**

+98 71 3647 4270

**Fax****Email**

masihifarzaneh@yahoo.com

**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*