Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 α-minimal essential medium (α-MEM) and then into fresh (fIVM). Intervention group 2: 50 germinal vesicles will be used in α-minimal essential medium (α-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 mediumin.

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

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Iran (Islamic Republic of)

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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 scienece
Inclusion/Exclusion criteria
Inclusion criteria: the age lower than 35 years old.
Exclusion criteria: endometriosis; poly cystic 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 α-minimal essential medium (α-MEM) and then randomly be into fresh (flVM).
Category
Treatment - Drugs

2

Description
Intervention group 2: 50 germinal vesicles will be used in

α-minimal essential medium (α-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

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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

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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

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MS in english teaching ,BS in anesthesia/English Consultant

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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