Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of gene expression profile in human cumulus cells influenced by different oocyte Pre-incubation times in infertile patients under the treatment in assisted reproduction technology cycles.

Protocol summary

Study aim

The purpose of this study was to determine changes in the expression profile of cumulus cells in genes under the influence of different pre-incubation time of human oocytes in patients undergoing assisted reproductive cycles.

Design

In this study, the participants were randomly allocated to one of the two groups of zero and three hours of oocyte pre- incubation based on random numbers obtained from internet sites. The number of people in each group is 10, which obtain according to a study in 2009, taking into account the first type error, α = 0.05 and the second type error was β = 10%.

Settings and conduct

This study is conducted at Akbar Abadi Hospital's Infertility Clinic. Participants will be randomly assigned to one of the groups after receiving sufficient information about the study groups and the consent form, without being informed of their study group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age aged 25 to 35 years, patients who are in the agonist cycle, infertile women with tubal problems, normal semen analysis according to WHO 2010 criteria Exclusion criteria: pelvic acute infection, coagulation disorder, cervicitis and vaginitis, cervix malignancy, BMI>35, endometriosis (grade 3 &4), polycystic ovarian syndrome, oocyte number less 2 and further 15

Intervention groups

Intervention group 1: The oocytes are not affected by pre- incubation. Intervention group 2: The oocytes are affected by pre-incubation for 3 hours.

Main outcome variables

Primary outcome variable: Determine the preincubation time appropriate for the human ovum, according to the molecular results for approaching the highest fertility and embryo quality. Secondary outcome variable: The determination of gene expression profiles that are involved in these pathways and can serve as a marker for the quality of oocytes and embryos.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180603039965N1**
Registration date: **2018-07-27, 1397/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**
Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Mehdi Mehdizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of gene expression profile in human cumulus cells influenced by different oocyte Pre-incubation times in infertile patients under the treatment in assisted reproduction technology cycles.

Public title

The effect of oocyte per-incubation time on the cumulus gene profile

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

patients who are in the agonist cycle infertile women with tubal factor normal semen analysis according to WHO 2010

Exclusion criteria:

pelvic acute infection coagulation disorder cervicitis and vaginitis cervix malignancy BMI>35 endometriosis(grade 3 &4) polycystic ovarian syndrome oocyte number less than 2 and more than 15

Age

From **25 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers are obtained from internet sites and patients are assigned to control and intervention groups according to these random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants do not know which intervention group they will be assigned to until the end of the study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat West Highway between of Sheikh Fazlallah and Shahid Chamran intersection

City

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Province

Tehran

Postal code

1449614535

Approval date

2018-04-30, 1397/02/10

Ethics committee reference number

IR.IUMS.REC.1396.31837

Health conditions studied

1

Description of health condition studied

Determination of optimal condition to elevate invitro fertilization rate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Gene expression profile of cumulus cells

Timepoint

At the beginning and 3 hours after pre- incubation

Method of measurement

RNA Sequencing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 0 hours oocyte pre- incubation before intracytoplasmic sperm injection

Category

Other

2

Description

Intervention group 2: 3 hours oocyte pre- incubation before intracytoplasmic sperm injection

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbar Abadi hospital
Full name of responsible person
Zahra Zandieh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences
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Mehdi Mehdizadeh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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