

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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, $\alpha = 0.05$ and the second type error was $\beta = 10\%$.

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)

Phone

+98 21 8670 4569

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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 science

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
Tehran
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

Street address

Molavi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyyed Kazem Malakouti

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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

Full name of responsible person

Mehdi Mehdizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Assistant Professor

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Other areas of specialty/work

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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