

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of gene expression of immature oocytes before and after Ooplasmic transfer in Unexplained Infertile women in Mirza kochak Khan Hospital(2012-2013)

Protocol summary

Summary

The essential role of ooplasm in maturing and activating oocytes and in the primary stages of embryonic division is well documented; however, little is known about the details of this process. Cohen et al. (1997) first reported successful human impregnation after transferring the cytoplasm of the donated oocytes to those of the infertile women. Their objective was to restore the normal growth of high-risk oocytes caused by ooplasmic defect. They also reported the birth of over 30 healthy babies by the end of 2004 by the direct injection of the cytoplasm from donated (either frozen or fresh) oocytes to defective ones using modified ICSI. This technique includes the injection of 10-15% of the cytoplasm from a donated oocyte to a target oocyte in order to enhance its genesis under laboratory conditions. The cytoplasm of a mature oocyte can lead to the maturity of a defective oocyte, due to having regulators of cell cycle, healthy mitochondria, microtubules involved in cell division, DNA replication enzymes, and enhancing the level of mRNA. This technique can be used for women who have had repeated IVF failure or unsuccessful implantation due to poor quality embryos in their previous cycles. According to the studies conducted on the expression levels of genes involved in the natural trend of development and evolution of human oocyte, the present study aims to evaluate the changes in the expression of genes that occur in an oocyte after cytoplasmic injection and compare its results to the oocytes in the control group. It is noteworthy that the present study will be conducted on available oocytes whose usage will not pose any ethical considerations, including donated and immature oocytes. In the present work, immature oocytes will be categorized into two categories: 1- 30 immature oocytes as the intervention group: 15% cytoplasm is injected to them; afterwards, they will be cultivated in G1 medium culture and kept in incubator for 24 hours. Then, Trizol

solution will be added to them and they will be kept at -80 °C. 2- 60 immature oocytes as the control group, which itself is further categorized into two groups: a. 30 immature oocytes will be put in the Trizol solution immediately after pick up, and will be kept at -80 °C. b. 30 immature oocytes will be cultivated in G1 medium culture and kept in incubator for 24 hours. Then, Trizol solution will be added to them and they will be kept at -80 °C. After the sampling, the oocytes in each group will be pooled separately. Then, their RNA will be extracted and cDNA will be synthesized. Finally, the expression level of target genes will be determined using the Q RT-PCR in each group. The level of morphological changes in the oocytes of each group (both intervention and control) will also be determined after 24 hours of incubation using inverted microscope.

General information

Acronym

human immature oocyte and ooplasmic transfer

IRCT registration information

IRCT registration number: **IRCT2013090512307N1**

Registration date: **2013-09-05, 1392/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-05, 1392/06/14

Registrant information

Name

Fatemeh Sadat Hoseini

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-20, 1392/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of gene expression of immature oocytes before and after Ooplasmic transfer in Unexplained Infertile women in Mirza kochak Khan Hospital(2012-2013)

Public title

Comparison of gene expression of immature oocytes before and after Ooplasmic transfer in Unexplained Infertile women in Mirza kochak Khan Hospital(2012-2013)

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: age 18-40 yrs; normal level of serum FSH/ LH/ PRL/ TSH; persistent mature and immature oocytes at OPU; long agonist protocol ovarian stimulation; mild endometriosis-Male Infertility-Unexplained Infertility-Tubal Factor. Exclusion criteria: PCO; moderate/severe Endometriosis and Genetic diseases.

Age

From 18 years old to 40 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of Research of Tehran University of Medical Science

Street address

Floor 6th, Deputy of Research of Tehran University of Medical Science, Ghods street, Keshavarz Blvd.

City

Tehran

Postal code

1417653761

Approval date

2012-10-21, 1391/07/30

Ethics committee reference number

130/1743/91/3

Health conditions studied

1

Description of health condition studied

IVF, ART

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of ooplasm transfer into immature oocytes on the gene expression of TGF-B family

Timepoint

end of sampling

Method of measurement

Real Time PCR

2

Description

The effect of ooplasm transfer into immature oocytes on the gene expression of cycle cell

Timepoint

end of sampling

Method of measurement

Real Time PCR

3

Description

The effect of ooplasm transfer into immature oocytes on the gene expression of apoptosis

Timepoint

end of sampling

Method of measurement

Real Time PCR

4

Description

The effect of ooplasm transfer into immature oocytes on the gene expression of ATPase 6 in mitochondria

Timepoint

end of sampling

Method of measurement

Real Time PCR

5

Description

The effect of ooplasm transfer into immature oocytes on the gene expression of DNA repairing

Timepoint

end of sampling

Method of measurement

Real Time PCR

6

Description

The effect of ooplasm transfer into immature oocytes on the gene expression of mitotic spindle

Timepoint

end of sampling

Method of measurement

Real Time PCR

Secondary outcomes

1

Description

The effect of ooplasm transfer into immature oocytes on the morphology after 24 hrs oocyte incubation

Timepoint

24 hrs after oocytes culture

Method of measurement

Invert Microscope

Intervention groups

1

Description

human Ooplasm Transfer 10-15% to immature oocytes and then oocytes culture for 24 hours in 5% co2 incubator.

Category

Other

2

Description

control group 1, not intervention

Category

Other

3

Description

control group 2, oocytes culture for 24 hours in 5% co2 incubator

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mirza Kochak Khan Hospital

Full name of responsible person

Dr. Naser Salsabili Dr. firoozeh Akbari Asbagh

Street address

North Negatollahi ST.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Akbar Fotohi

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Floor 6th, Deputy of Research of Tehran University of Medical Science, Ghods street, Keshavarz Blvd.

City

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Grant name

پایان نامه دکترای تخصصی

Grant code / Reference number

91023018324

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

Yes

Title of funding source

Tehran University of Medical Science

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Mohammad Hossein Noori Mugahi

Position

prof. of Histology & Embryology

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Fatemeh Sadat Hoseini

Position

Research employee and candidate of PhD of Reproductive Biology

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Email**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