Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 in 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 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

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Name of organization / entity

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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 scienece
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-Un Explained 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/د

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 mitcondria
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 after24 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
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North Negatollahi ST.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran
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

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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