Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of iodine on the rate of apoptosis and proliferation in oocytes of infertile women with diminished ovarian reserve

Protocol summary

Study aim

Investigating the effect of iodine on the rate of apoptosis and proliferation in oocytes of infertile women with diminished ovarian reserve

Design

Type of study: semi-experimental before, after Number: 10 patients with diminished ovarian reserve and candidates for frozen embryo storage The study does not have randomization and each patient is compared to himself before and after receiving iodine

Settings and conduct

Location: Imam Khomeini Hospital, Tehran Research steps include: Selection of patients Measurement of urine iodine Stimulation of the ovaries with the antagonist protocol, puncture of the ovaries and collection of cumulus cells Determining the quality of oocytes, evaluating PCNA gene expression of cumulus cells with real-time PCR and evaluating apoptosis with flowcytometry (before receiving iodofolic) Receiving oral iodofolic containing 150 micrograms of iodine for two months Re-stimulation of the ovaries in the second stage and repeating the above evaluations

Participants/Inclusion and exclusion criteria

Inclusion criteria Ages between 25 to 42 years, Normal thyroid function with no history of thyroid disorders including hypothyroidism or hyperthyroidism, Absence of any underlying disease, antral follicle count between 3-5, AMH level between 1-0.1 (ng/mL) (based on Bologna criteria) (Ferraretti AP et al, 2014) Exclusion criteria Drug addiction, smoking, alcohol , presence of endometriosis , history of repeated miscarriages

Intervention groups

Infertile women with a diminished ovarian reserve who are candidate for embryo preservation will be evaluated for apoptosis and proliferation before and after two months of taking iodofolic tablets containing 150 micrograms of iodine.

Main outcome variables

Evaluation of the impact of iodine on the rate of apoptosis and proliferation of cumulus cells and its relationship with oocyte quality to enhance treatment success.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240819062811N1**
Registration date: **2024-09-07, 1403/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-07, 1403/06/17**
Update count: **0**

Registration date

2024-09-07, 1403/06/17

Registrant information

Name

Masoumeh Masoumi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1616

Email address

m_masoumi@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-31, 1403/06/10

Expected recruitment end date

2024-10-31, 1403/08/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of iodine on the rate of apoptosis and proliferation in oocytes of infertile women with diminished ovarian reserve

Public title
Investigating the effect of iodine on oocytes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ages between 25 to 42 years, Normal thyroid function with no history of thyroid disorders including hypothyroidism or hyperthyroidism, Absence of any underlying disease, antral follicle count between 3-5, AMH level between 1-0.1 (ng/mL) (based on Bologna criteria) (Ferraretti AP et al, 2014)
Exclusion criteria:
Drug addiction, smoking, alcohol , presence of endometriosis , history of repeated miscarriages
Age
From **25 years** old to **42 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
Oocyte samples of patients who are candidates for oocyte storage before and after receiving iodine
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, end of Keshavarz Boulevard, Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2024-08-06, 1403/05/16
Ethics committee reference number
IR.TUMS.IKHC.REC.1403.206

Health conditions studied

1

Description of health condition studied
Infertile women with diminished ovarian reserve
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Apoptosis and proliferation of oocyte
Timepoint
The first stage before taking iodine and the second stage two months after taking iodine
Method of measurement
Apoptosis by flow cytometry and proliferation by real-time PCR

Secondary outcomes

empty

Intervention groups

1

Description
control group: Infertile women with a diminished ovarian reserve who are candidate for embryo preservation before taking iodofolic tablets. Intervention group: Infertile women with a diminished ovarian reserve who are candidate for embryo preservation after two months of taking iodofolic tablets of Dorsa Daro company containing 150 micrograms of iodine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Masoumeh Masoumi
Street address
Imam Khomeini Hospital, Waliasr Reproductive Health Research Center, end of Keshavarz Boulevard, Tehran
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masomeh_masomi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
Street address
Keshavarz Boulevard, corner of Qods St., Tehran University of Medical Sciences, 6th floor, Research and Technology Vice-Chancellor
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1461884513
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vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Masoumeh Masoumi
Position
Research expert
Latest degree
Ph.D.
Other areas of specialty/work
Infertility
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Imam Khomeini Hospital, Vali Asr Reproductive Health Research Center, end of Keshavarz Boulevard, Tehran
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Sharing, if necessary, will be done after the end of the study.

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