Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the efficiency of two commercial culture media (RS Medical and LifeGlobal) for embryo culture after ICSI: A randomized clinical trial

Protocol summary

Study aim

The present study aimed to compare the key performance indicators (KPIs) and clinical outcomes resulting from embryos cultured in two commercial media for embryo culture LifeGlobal and Ravan Sazeh (RS) Medical.

Design

Four sibling injected metaphase II oocytes were randomly allocated and cultured in the following groups: 1- Injected metaphase II oocytes cultured in LifeGlobal 2- Injected metaphase II oocytes cultured in RS Medical

Settings and conduct

Infertility clinics located at Erfan Niayesh Hospital Tehran, Iran and Mehr Fertility Research Center, Rasht, Iran

Participants/Inclusion and exclusion criteria

The inclusion criteria included infertile couples planned for their first intracytoplasmic sperm injection/embryo transfer (ICSI/ET) cycle with women younger than 35 years old who had body mass index (BMI) under 30 kg/m2, normal serum follicle-stimulating hormone (FSH) levels (FSH< 12 IU/L) on day 2 or 3 of menstrual cycle, and were scheduled to undergo gonadotropin-releasing hormone (GnRH) antagonist protocol as their controlled ovarian hyperstimulation (COH) treatment and had more than 8 mature (metaphase II) oocytes. The exclusion criteria were presence of any uterine lesions such as fibroids and endometrial polyps, hydrosalpinx, adenomyosis, intrauterine adhesions, endometriosis, uterine congenital anomalies, hormonal disruptions, inflammatory and autoimmune diseases and syndromes, history of ectopic pregnancy and miscarriage, ovarian hyperstimulation syndrome (OHSS), and having less than 8 mature (metaphase II) oocytes.

Intervention groups

1- Injected metaphase II oocytes cultured in LifeGlobal 2- Injected metaphase II oocytes cultured in RS Medical

Main outcome variables

Fertilization rate, cleavage rate, day 3 embryo development rate, blastocyst development rate, embryo implantation rate, clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201031049203N1**
Registration date: **2021-04-19, 1400/01/30**
Registration timing: **prospective**

Last update: **2021-04-19, 1400/01/30**
Update count: **0**

Registration date

2021-04-19, 1400/01/30

Registrant information

Name
Hossein Hooseinirad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4613 5219

Email address
hossein.hosseinirad@rsmedical.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the efficiency of two commercial culture media (RS Medical and LifeGlobal) for embryo culture after ICSI: A randomized clinical trial

Public title
Comparison of two commercial embryo culture media
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile couples planned for their first ICSI/ET cycle Women younger than 35 years old who had body mass index (BMI) under 30 kg/m2, Normal serum follicle-stimulating hormone (FSH) levels (FSH< 12 IU/L) on day 2 or 3 of menstrual cycle Undergo gonadotropin-releasing hormone (GnRH) antagonist protocol as their controlled ovarian hyperstimulation (COH) treatment More than 8 mature (metaphase II) oocytes
Exclusion criteria:
Age
From **20 years** old to **35 months** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **4**
Mature MII oocyte
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using restricted randomization (individual randomization) by random allocation rule. Allocation concealment will be conducted using sequentially numbered, sealed, opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients, physicians, outcome assessor, and statistician were all kept blinded during the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Research Ethics committee of Islamic Azad University-Tonekabon Branch
Street address
Tonekabon Branch, Islamic Azad University, Tonekabon, Mazandaran Province, Iran
City
Tonekabon
Province
Mazandaran
Postal code
۴۶۸۴۱۶۱۱۶۷
Approval date
2021-03-06, 1399/12/16
Ethics committee reference number
IR.IAU.TON.REC.1399.122

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fertilization rate
Timepoint
22 hours after ICSI
Method of measurement
Microscopic observation

2

Description
Cleavage rate
Timepoint
Day 2 after ICSI
Method of measurement
Microscopic observation

3

Description
Day 3 embryo development
Timepoint
Day 3 after ICSI
Method of measurement
Microscopic observation

4

Description
Blastocyct Development Rate
Timepoint
Day 5 after ICSI
Method of measurement
Microscopic observation

5

Description
Implantation Rate
Timepoint
Fourteen days after embryo transfer
Method of measurement
Ultrasonography

6

Description
Clinical pregnancy rate
Timepoint
Fourteen days after embryo transfer
Method of measurement
Ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Embryo culture in RS Medical commercial media. Embryo culture medium will be prepared in 25 micro litter droplets under mineral oil overlay. Injected oocytes will be cultured in these droplets until day 5 of embryo development.
Category
N/A

2

Description
Control group: Embryo culture in LifeGlobal commercial media. Embryo culture medium will be prepared in 25 micro litter droplets under mineral oil overlay. Injected oocytes will be cultured in these droplets until day 5 of embryo development.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic of Erfan Niayesh Hospital
Full name of responsible person
Dr. Somaye Keshavarzi
Street address
Bahar street, North Jannat-Abad, Erfan Niayesh Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Mohsen Mohammadi
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Tonekabon Branch, Islamic Azad University, Tonekabon, Mazandaran Province, Iran
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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
Islamic Azad University
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

Dr. Hossein Hosseinirad
Position
Embryologist
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Bahar street, North Jannat-Abad, Erfan Niayesh Hospital
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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Ph.D.
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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
We have not decided to publish these data.
When the data will become available and for how long
6 months after the study is finished.
To whom data/document is available
Infertility specialties
Under which criteria data/document could be used
For further clinical studies.
From where data/document is obtainable
Send email to the corresponding person.
What processes are involved for a request to access data/document
Approval from the clinic, approval from the corresponding person.
Comments