

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

development rate, blastocyst development rate, embryo implantation rate, clinical pregnancy rate

#### 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/m<sup>2</sup>, 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

#### 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.hosseini@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/m<sup>2</sup>, 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**

Blastocyst 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1476919491

**Phone**

+98 21 4979 6000

**Email**

somayeh\_keshavarzi@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Mohsen Mohammadi

**Street address**

Tonekabon Branch, Islamic Azad University, Tonekabon, Mazandaran Province, Iran

**City**

Tonekabon

**Province**

Mazandaran

**Postal code**

۴۶۸۴۱۶۱۱۶۷

**Phone**

+98 11 5427 0736

**Email**

mohsenmohammadi580101@gmai.com

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

1476919491

**Phone**

+98 21 4979 6000

**Email**

rad6438@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Shahrokh Paktinat

**Position**

Embryologist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

**Street address**

Bahar street, North Jannat-Abad, Erfan Niayesh Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1476919491

**Phone**

+98 21 4979 6000

**Email**

sh.paktinat@gmail.com

## Person responsible for updating data

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

1476919491

**Phone**

+98 21 4979 6000

**Email**

rad6438@gmail.com

## 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**