

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluating the Role of Cosmetic Micromanipulation on Vitrified-Warmed Human Cleavage stage Embryos on Assisted Reproductive Technology Outcome

Protocol summary

Summary

The aim of this study is evaluating the role of cosmetic micromanipulation on vitrified-warmed human cleavage stage embryos on assisted reproductive technology outcome. 96 Patients that are undergoing frozen embryo transfer (FET) with similar clinical characteristics are included in this prospective randomized study. They are divided into three groups of cosmetic micromanipulation (CM; n=32), laser assisted zona hatching (LAH; n=32) and control(n=32). CM is defined as removal of fragments and coarse granules from the vitrified-warmed embryos before embryo transfer (ET). The days 2 or 3 vitrified-warmed embryos with grades of B or C are included in this study. The patients with multinucleated or revitrified-warmed embryos are excluded from study. In CM group, a few hours after embryo warming and morphology evaluation, the embryo are subjected to CM after LAH. Whereas; in LAH group warmed embryos are subjected to LAH only. After overnight incubation, cell division and morphology of embryos are evaluated and divided embryos are transferred. the ART outcome are followed up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030421332N1**
Registration date: **2015-06-01, 1394/03/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-01, 1394/03/11

Registrant information

Name

Somayyeh Safari

Name of organization / entity

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Yazd,

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7088

Email address

ssafari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd and Research and Clinical Center for Infertility, Yazd

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Role of Cosmetic Micromanipulation on Vitrified-Warmed Human Cleavage stage Embryos on Assisted Reproductive Technology Outcome

Public title

Evaluating the Role of Cosmetic Micromanipulation on Vitrified-Warmed Human Cleavage stage Embryos on Assisted Reproductive Technology Outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients undergoing IVF/ICSI who have fragmented vitrified-warmed days 2 or 3 embryos with morphology grades of B and C. Exclusion criteria: Patients with multi-nucleated or revitrified-warmed embryos

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

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

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences

Street address

Bouali Ave, Safaeiyeh

City

Yazd

Postal code

8916877391

Approval date

2013-06-20, 1392/03/30

Ethics committee reference number

174

Health conditions studied

1

Description of health condition studied

infertile patients

ICD-10 code

N97

ICD-10 code description

Female infertility

2

Description of health condition studied

infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

14 days after transfer of embryos into uterine

Method of measurement

measuring bhCG level in blood

2

Description

Clinical pregnancy

Timepoint

heart beat in 7th week of gestation

Method of measurement

observation of heart beat with ultrasound

Secondary outcomes

1

Description

Cell division in embryo

Timepoint

overnight after vitrified embryo warming

Method of measurement

by inverted microscope

Intervention groups

1

Description

Intervention: assisted laser hatching and microsurgery on embryo for removal the fragments or granules surrounded the blastomeres

Category

Other

2

Description

control: without any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences

Full name of responsible person

Somayyeh Safari

Street address

Bouali Ave, Safaeiyeh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Dr.Ali Mohammad Abdoli

Street address

Bouali Ave, Safaeiyeh

City

yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences, Yazd

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

Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Somayyeh Safari

Position

Ph.D candidate in reproductive medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Khalili

Position

PhD of anatomy

Other areas of specialty/work

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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