Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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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Person responsible for updating data

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Position
Ph.D candidate in reproductive biology

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