Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Intrauterine delivery of Dexamethasone for repeated implantation failure: a RCT

Protocol summary

Study aim
Increased pregnancy and childbirth lead to the birth of a live baby in patients with recurrent implantation failure.

Design
Clinical trial with control group, with parallel groups, single blind, randomized, on 60 patients. The rand function of the Excel software was used for randomization.

Settings and conduct
A questionnaire is completed for patients who meet the criteria for admission to the study and after obtaining informed consent. According to the random list, patients are divided into intervention and control groups. In both groups, after baseline ultrasound on the second day of the cycle, the ART cycle begins . In interventional patients on days 9 and 12 of intrauterine injection of dexamethasone 600µL (5 mg / ml) The fetus is transferred slowly with a fetal catheter. In patients with the control group, the same normal volume of sterile saline is prescribed.

Participants/Inclusion and exclusion criteria
This study is clinical trial of patients with recurrent idiopathic implantation failure. Patients with at least twice a history of ART and having a total of six transplanted grade one embryos if they have the criteria to enter the study after obtaining informed consent. Criteria for entering the study: • Minor age 40 years • Proper ovarian storage (AMH) above one • At least twice the previous ART by transferring at least six first-degree embryos • Healthy uterine cavity in ultrasound and hysteroscopy (absence of uterine anomaly, endometrial polyp, uterine myoma) • Absence of endocrinopathy and autoimmune and thrombophilic disease • Normal karyotype

Intervention groups
According to the random list, patients are divided into intervention and control groups.

Main outcome variables
Endometrial thickness, implantation, pregnancy (ßHCG-positive-clinical pregnancy), live birth, miscarriage, ectopic pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200502047261N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **retrospective**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date
2023-02-20, 1401/12/01

Registrant information

Name
zahara sadat khonsarian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2296 7790

Email address
hsn.khosropour@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2019-05-31, 1398/03/10

Actual recruitment end date
2020-03-19, 1398/12/29

Trial completion date
2020-03-19, 1398/12/29

Scientific title
Intrauterine delivery of Dexamethasone for repeated implantation failure: a RCT

Public title
Intrauterine delivery of Dexamethasone for repeated implantation failure: a RCT

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age under 40 years (AMH) above one At least twice the previous ART by transferring at least six grade one embryos Healthy uterine cavity in ultrasound and hysteroscopy (lack of uterine anomaly, endometrial polyp, uterine myoma) Absence of endocrinopathy and autoimmune and thrombophilic diseases Normal karyotype Absence of severe male infertility Absence of moderate or severe endometriosis Absence of a specific cause for implantation in previous ARTs Absence of hydrosalpenx

Exclusion criteria:
Age over 40 years (AMH) below one Abnormal uterine cavities on ultrasound and hysteroscopy (with uterine anomalies, endometrial polyps, uterine myomas) Endocrinopathy and autoimmune and thrombophilic diseases Abnormal karyotype Severe male infertility Existence of a specific cause of non-implantation in previous ARTs Existence of hydrosalpinx Severe or moderate endometriosis

Age
To **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on random sampling, patients are divided into intervention and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
For patients who have the criteria to enter the study, after obtaining informed consent, according to the decision of the ethics committee of Tehran University of Medical Sciences, a questionnaire will be completed and they are unaware of the allocation of the study group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research, School of Medicine, Tehran University of Medical Sciences

Street address
headquarters of Tehran University of Medical Sciences, Intersection of Keshavarz Boulevard and Quds Street

City
Tehran

Province
Tehran

Postal code
141765376

Approval date
2019-05-13, 1398/02/23

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.084

Health conditions studied

1

Description of health condition studied
Patients with repeated implantation failure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pregnancy

Timepoint
According to the random list, patients are divided into intervention and control groups.In both groups, after basic ultrasound on the second day of the cycle, the ART cycle begins, and ovarian stimulation information is recorded for each patient. In patients in the 9 and 12 days of intramuscular injection of dexamethasone 600µL (5mg / ml) with a fetal transfer catheter, the intervention is performed slowly.In patients with the control group, the same normal volume of sterile saline is prescribed.Both groups are followed by transvaginal ultrasound while taking ART.When at least two follicles are seen, 10,000 HCG units are injected and 36 hours later the pancreas is transplanted under vaginal ultrasound. The ultrasound is performed two weeks later and the pregnancy sac is examined.

Method of measurement
Pregnancy test(ßHCG)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In the control group, on days 9 and 12, normal intrauterine injection of 600µL sterile saline (5 mg / ml) is performed with a fetal transfer catheter.
Category
Placebo

2

Description
Intervention group: In patients in the 9 and 12 days of intramuscular injection of dexamethasone 600µL (5 mg / ml) with a fetal transfer catheter.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Saeid Mehrpour
Street address
Jalal-e-Al-e-Ahmad Hwy
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Fax
+98 21 8863 3039
Email
shariatihosp@tums.ac.ir
Web page address
http://shariati.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
shahin akhoundzade
Street address
Intersection of Keshavarz Boulevard and Quds Street, headquarters of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
141765376
Phone
+98 21 6640 5357
Fax
+98 21 8895 3003
Email
deanmed@tums.ac.ir
Web page address
http://medicine.tums.ac.ir/college
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
Zahra sadat Khonsarian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No.13, Nahid Ave, Vafamanesh Ave., Heravi Sq
City
Tehran
Province
Tehran
Postal code
1668756738
Phone
+98 21 2296 7790
Email
hsn.khosropour@gmail.com

Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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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
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