

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Assessing the effect of supplemental injectable progesterone on complicated monochorionic diamnionic twin pregnancy with radiofrequency ablation with cervical length of 25 mm or above on TVS

Protocol summary

Study aim

Assessing the effect of supplemental injectable progesterone on complicated monochorionic diamnionic twin pregnancies radiofrequency ablated with cervical length of 25 mm in TVS

Design

randomized single-blinded (analyzer), controlled clinical trial, phase 3; sample size 80

Settings and conduct

This study performed at Yas women hospital patients in the intervention group were pregnancies who underwent RFA for one of the twins and had a cervical length longer than 25mm who were administered 17-hydroxyprogesterone caproate control group were complicated twin pregnancies undergone RFA for randomization equal to the number of patients a & b letters were put in a pocket and before each RFA procedure a letter has been drawn to determine allocation of the patient in case versus control group the data analyzer was blinded to group allocations

Participants/Inclusion and exclusion criteria

complicated monochorionic diamnionic twin pregnancies radiofrequency ablated with cervical length of 25 mm in TVS exclusion criteria : history of cervical insufficiency or recurrent pregnancy loss of second trimester history of preterm delivery in previous pregnancies cerclage twin-twin transfusion syndrome

Intervention groups

complicated monochorionic diamnionic twin pregnancies radiofrequency ablated with cervical length of 25 mm in TVS patients in the intervention group were administered a dose of 17 hydroxyprogesterone caproate 250mg intramuscular and the same dose was prescribed weekly until 36 weeks gestation for control group, patients underwent radiofrequency ablation and no further drug intervention was done

Main outcome variables

Duration of pregnancy; preterm premature rupture of membranes; neonate admission to NICU.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046496N1**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **retrospective**

Last update: **2020-03-24, 1399/01/05**

Update count: **0**

Registration date

2020-03-24, 1399/01/05

Registrant information

Name

Forough Jabbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8843 7182

Email address

f-jabbari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-17, 1397/12/26

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessing the effect of supplemental injectable progesterone on complicated monochorionic diamnionic twin pregnancy with radiofrequency ablation with cervical length of 25 mm or above on TVS

Public title
Assessing the effect of supplemental injectable progesterone on complicated monochorionic diamnionic twin pregnancy with radiofrequency ablation with cervical length of 25 mm or above on TVS

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 complicated monochorionic diamnionic twin pregnancy with radiofrequency ablation with cervical length of 25 mm or above on TVS intrauterine growth restriction or anomaly of one of the twins
Exclusion criteria:
 personal history of cervical insufficiency or second trimester recurrent pregnancy loss history of preterm delivery in previous pregnancies cerclage twin-twin transfusion syndrome (TTTS)

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization To the number of samples in each group, letters A or B were written on cards and put in a pocket. Prior to each intervention a card was taken out determining the patient allocation to case or control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Follow up and result assessment of patients were performed by health care providers who were blind to allocation and the final results were available to the researcher and data analyzer by codes A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran national committee of ethics in biomedical research

Street address

Karim khan st

City

Tehran

Province

Tehran

Postal code

1597856511

Approval date

2019-02-26, 1397/12/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.861

Health conditions studied

1

Description of health condition studied

complicated monochorionic diamnionic twin pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

decreasing rate of preterm delivery

Timepoint

termination of pregnancy

Method of measurement

tele-follow up

Secondary outcomes

1

Description

neonate admission to NICU

Timepoint

after delivery

Method of measurement

tele-follow up

2

Description

preterm premature rupture of membranes

Timepoint

termination of pregnancy

Method of measurement

tele-follow up

forouq.jabbari@gmail.com

Intervention groups

1

Description

Intervention group: monochorionic twin pregnancies complicated with anomalous fetus or selective IUGR of a co-twin with cervical length more than 25 millimeters undergoing radiofrequency ablation, supplemental injectable progesterone in the form of 17hydroxyprogesterone caproate will be administered intramuscularly and the same dose will be injected weekly until 36 weeks gestation. the patients will be compared to the control group for whom , only the RFA is done and no further drug administration is performed.

Category

Treatment - Drugs

2

Description

Category

empty

3

Description

Control group: monochorionic complicated twin pregnancies by anomalous fetus or selective IUGR and a cervical length more than 25mm, undergo ablation of the abnormal co-twin with radiofrequency and no supplemental progesterone and pregnancy outcome is followed.RFA is a single session procedure done through a needle using radiofrequency waves, resulting in occlusion of the abnormal co-twin cord and intrauterine fetal death while the other continue to grow.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Women Hospital

Full name of responsible person

Forough-o-Zaman Jabbari

Street address

Karim Khan

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Forough-o-Zaman Jabbari

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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

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

Fough-o-Zaman Jabbari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Rahimi Sharbaaf

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Forough-o-Zaman

Position

Resident

Latest degree

Medical doctor

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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