Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The cheanges of betamethasone on non-stress test (NST) and Doppler ultrasound parameters in fetuses with Intra uterine growth retardation in pregnant women referred to Imam Khomeini Hospital in Sari

Protocol summary

Study aim

Determining the changes of betamethasone on non-stress test (NST) and Doppler ultrasound parameters in fetuses with intrauterine growth restriction in pregnant women referred to Imam Khomeini Hospital, Sari

Design

Prospective cohort, determination of sample size by head count, three-way blinding, with two exposure and control groups

Settings and conduct

Prospective cohort study in Imam Khomeini Hospital, Sari, in the form of a census. Patients are selected according to the entry and exit criteria. The informed consent form will also be obtained after explaining the study to them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: singleton pregnancy Gestational age of 28 to 32 weeks and the threat of preterm delivery Fetal growth restriction confirmed by ultrasound based on fetal growth percentage Exit criteria: Arrhythmia or fetal heart problems Congenital anomaly of the fetus Symptoms of active infection of the mother Premature rupture of the amniotic sac (PPROM) Pregnant women receiving benzodiazepines and narcotics Women who give birth during the study Mother's underlying diseases (hypertension, diabetes)

Intervention groups

First, non-stress test of NST for 20 minutes and Doppler of the umbilical MCA artery is directed to the patient. Then 2 doses of betamethasone ampoule (12 mg) are injected intramuscularly 24 hours apart. After 12 hours (day 1), 24 hours (day 2) and 36 hours (day 2), NST is performed again for 20 minutes. NST will be performed in all patients in supine and left lateral position (to prevent supine hypotension). The range of time for Doppler ultrasound (24 to 36 hours) will be after receiving two doses of betamethasone.

Main outcome variables

Doppler ultrasound parameters of the umbilical artery and MCA, Determining the base heart rate, beat-to-beat variability, increase or decrease in fetal heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231015059721N1**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Roghayeh Bagherzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 775 0968

Email address

hrwaiter1382@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The cheanges of betamethasone on non-stress test (NST) and Doppler ultrasound parameters in fetuses with Intra uterine growth retardation in pregnant women referred to Imam Khomeini Hospital in Sari

Public title

Changes of betamethasone on non-stress test (NST) and Doppler ultrasound parameters in fetuses with growth restriction

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

1- Singleton pregnancy 2- Gestational age of 28 to 32 weeks and threat of preterm delivery 3- Fetal growth restriction confirmed by ultrasound based on fetal growth percentage

Exclusion criteria:

1- Arrhythmia or fetal heart problems 2- Congenital anomaly of the fetus 3- Symptoms of active infection of the mother 4- Premature rupture of the amniotic sac (PPROM) 5-Pregnant women receiving benzodiazepines and narcotics 6- Women who give birth during the study 7- Mother's underlying diseases (hypertension, diabetes

Age

From **14 years** old to **55 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

All people including researchers, participants, outcome assessors and analysts will be blinded in this study.Only the clinical caregiver will be aware of the study process due to the protection of the patients (the clinical caregiver is the nurse, midwife or doctor of the patients who are not part of the research team, but are aware of the study process)

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences Research Center

Street address

Sari, Ayatollah Taleghani, Moalem Street, Moalem Square

City

sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2022-09-27, 1401/07/05

Ethics committee reference number

IR.MAZUMS.IMAMHOSP.1402059

Health conditions studied

1

Description of health condition studied

In fetuses with growth restriction in pregnant women referred to Imam Khomeini Hospital in Sari

ICD-10 code

Z35.2

ICD-10 code description

Z35.2

Primary outcomes

1

Description

Determination of Doppler ultrasound parameters of the umbilical artery and MCA, determination of the basic fetal heart rate and beat-to-beat variability of the fetal heart rate and the increase or decrease of the fetal heart rate.

Timepoint

First, a non-stress test of NST for 20 minutes and Doppler of the umbilical MCA artery were performed for the patient, then 2 doses of betamethasone ampoule (12 mg) were injected into the patient at an interval of 24 hours. After 12 hours (day 1), 24 hours (day 2) and 36 hours (day 2), NST is performed again for 20 minutes. Time range of Doppler ultrasound (24 to 36 hours) after receiving two doses of betamethasone.

Method of measurement

Demographic and clinical characteristics questionnaire, non-stress test before and 12, 24 and 36 hours after the

injection of two doses of betamethasone and doppler ultrasound 24 to 36 hours after the injection of the first dose of betamethasone

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Betamethasone receiving group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Zahra Rahmani
Street address
Mazandaran, Sari, Razi St., Imam Khomeini Educational and Medical Center (RA) Sari
City
sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3304 4000
Email
hrwaiter1382@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Clinical Research Development Unit of Imam Khomeini Medical Education Center (RA)
Full name of responsible person
Dr. Zahra Rahmani
Street address
Razi St., Clinical Research Development Unit, Imam Khomeini Medical Training Center, Sari
City
sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 1702
Email
hrwaiter1382@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Clinical Research Development Unit of Imam Khomeini Medical Education Center (RA)
Proportion provided by this source
60
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
Mazandaran University of Medical Sciences
Full name of responsible person
Zahra Rahmani
Position
Subspecialist in Perinatology, Mazandaran University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mazandaran, Sari, Razi St., Imam Khomeini Educational and Medical Center (RA) Sari
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Mazandaran
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۳۳۹۷۱-۴۸۱۵۷
Phone
+98 11 3304 4000
Email
refah@mazums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Zahra Rahmani
Position
Subspecialist in Perinatology, Faculty of Mazandaran University of Medical Sciences
Latest degree

Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Phone
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Email
refah@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
roghayeh bagherzadeh

Position
Resident of the Gynecology and Obstetrics specialization course

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Mazandaran, Sari, Razi St., Imam Khomeini Educational and Medical Center (RA) Sari

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Phone
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Email
hrwaiter1382@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Data collection is done at Imam Khomeini (RA) Hospital in Sari. After data collection, it will be provided to the Research Center and Research Development Unit of Mazandaran University of Medical Sciences as research documentation.

When the data will become available and for how long
At least three months after the start of sampling

To whom data/document is available
Mazandaran University of Medical Sciences, Research Center of Mazandaran University of Medical Sciences, Research Development Unit of Mazandaran University of Medical Sciences and Iran Clinical Trial Center

Under which criteria data/document could be used
To inquire about the accuracy of the sampling process, only to the centers covered by the Ethics Committee of Mazandaran University and the Clinical Trial Center of Iran.

From where data/document is obtainable
Scientific responsible person of the project, Mazandaran University of Medical Sciences, Research Center of Mazandaran University of Medical Sciences, Research Development Unit of Mazandaran University of Medical Sciences

What processes are involved for a request to access data/document
Correspondence with Mazandaran University of Medical Sciences, Research Center of Mazandaran University of Medical Sciences, Research Development Unit of Mazandaran University of Medical Sciences

Comments