Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of progesterone administration effects on uterine vascular flow in pregnant women with intrauterine growth restriction fetus and preterm labor

Protocol summary

Summary

To evaluate the effects of progestrone administration on uterine vascular blood flow in pregnant women with confirmed intrauterine growth restriction or preterm fetus, 50 pregnant women with diagnosed intrauterine growth restriction and another 50 ones with preterm initiation of labor are enrolled and those with Concomitant administration of progesterone and tocolytics or receiving progesterone in previous pregnancy are excluded. Between 24 to 48 hours after administration of tocolytics, progestrone is administered vaginally everyday. Doppler Sonography parameters of maternal uterine arteries and fetal cerebral vascular perfusion are assessed at the time of admission and 24 hours and 2 week after completing the progestrone courses and compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203289338N1**
Registration date: **2012-06-14, 1391/03/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-06-14, 1391/03/25

Registrant information

Name

Mahnaz Jahani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of progesterone administration effects on uterine vascular flow in pregnant women with intrauterine growth restriction fetus and preterm labor

Public title

Effects of progesterone on uterine vascular flow in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women between 24 and 37 weeks of pregnancy; diagnosis of Intrauterin growth restriction or preterm labor; receiving progesterone between 24 to 48 hours after administration of tocolytics
Exclusion Criteria: Concomitant administration of progesterone and tocolytics; administration of progesterone in previous pregnancy; labor within upcoming 2 weeks; multiple gestations

Age
From **15 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
N/A
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
Tehran University of Medical Sciences
Street address
Research Deputy, Faculty of Medicine, Poursina Street, Keshavarz Blvd
City
Tehran
Postal code
Approval date
2012-04-28, 1391/02/09
Ethics committee reference number
2688/130/90/ɔ

Health conditions studied

1

Description of health condition studied
Preterm labor and IUGR Fetus
ICD-10 code
P05.9
ICD-10 code description
Slow fetal growth, unspecified

Primary outcomes

1

Description
S/D Umbilical Artery
Timepoint
1st and 14th days
Method of measurement
Color Doppler Sonography

2

Description
PI in middle cerebral artery
Timepoint
1st and 14th days
Method of measurement
Color Doppler Sonography

3

Description
RI in Uterine Artery
Timepoint
1st and 14th days
Method of measurement
Color Doppler Sonography

4

Description
PI in middle cerebral artery
Timepoint
1st and 14th days
Method of measurement
Color Doppler Sonography

5

Description
PSV in MCA
Timepoint
1st and 14th days
Method of measurement
Color Doppler Sonography

Secondary outcomes

empty

Intervention groups

1

Description
In preterm labor group, 40 mg vaginal progesterone is administered daily within 2 weeks and Doppler sonography parameters were assessed before and after administration
Category
Treatment - Drugs

2

Description
In IUGR group, 40 mg vaginal progesterone is administered daily within 2 weeks and Doppler sonography parameters were assessed before and after

administration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie Asr Hospital

Full name of responsible person

Dr Mahnaz Jahani

Street address

Keshavarz Bv, Imam Khomeini Complex, Valie Asr Hospital, Second Floor, Obstetrics and Gynecology Ward

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhondzadeh

Street address

Medical School Research Affairs, Poorsina Street, Keshavarz Blv

City

Tehran

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

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

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Jahani

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Web page address

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