

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of different dosage of progesterone on uterine and placental vascular resistance in women at risk of preterm birth

Protocol summary

Study aim

Effect of different dosage of progesterone on uterine and placental vascular resistance in women at risk of preterm birth

Design

Clinical trials with control group, with parallel groups, Non-random, single center trial. Sample size (3 groups of 30 control and intervention).

Settings and conduct

Amir Al-Momenin Hospital, Semnan. All three groups will initially undergo color Doppler ultrasound of the uterine vessels, umbilical artery, and middle cerebral artery of the fetus. In the first group 400 mg progesterone and in the second group 200 mg progesterone is given vaginally. and the third group is studied as a control group.

Participants/Inclusion and exclusion criteria

Pregnant women at risk of preterm birth. Inclusion criteria: Singleton pregnancy; Pregnancy age 24 to 33 weeks. Exclusion criteria: A history of intrauterine insemination (IUI); In vitro fertilization (IVF) history.

Intervention groups

Intervention group 1: In this group, a 400 mg progesterone suppository will be used vaginally according to the treatment protocol. Intervention group 2: In this group, a 200 mg progesterone suppository will be used vaginally according to the treatment protocol. Control group: Only for comparison with intervention group, no treatment is performed.

Main outcome variables

Uterine artery Resistance Index; Uterine artery Pulsatility Index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N48**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of different dosage of progesterone on uterine and placental vascular resistance in women at risk of preterm birth

Public title

Effect of progesterone on uterine and placental vascular resistance in women at risk of preterm birth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton pregnancy Pregnancy age 24 to 33 weeks

Exclusion criteria:

A history of intrauterine insemination (IUI) In Vitro

Fertilization history (IVF)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.SEMUMS.REC.1398.187

Health conditions studied

1

Description of health condition studied

Preterm labour

ICD-10 code

O60.0

ICD-10 code description

Preterm labor without delivery

Primary outcomes

1

Description

Uterine artery Resistance Index

Timepoint

Before and 48 hours after intervention

Method of measurement

Doppler ultrasound

2

Description

Uterine artery Pulsatility Index

Timepoint

Before and 48 hours after intervention

Method of measurement

Doppler ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, a 400 mg progesterone suppository will be used vaginally according to the treatment protocol.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, a 200 mg progesterone suppository will be used vaginally according to the treatment protocol.

Category

Treatment - Drugs

3

Description

Control group: Only for comparison with intervention group, no treatment is performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Mojgan Rahmadian

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mojgan Rahmadian

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Mojgan Rahmadian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parisa Amini

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available