

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A clinical trial to comparison the effectiveness of 17 α -Hydroxyprogesterone caproate with routine prenatal care on prevention of preterm labor in patients with a history of preterm labor.

Protocol summary

Study aim

The effectiveness of 17 α -Hydroxyprogesterone caproate with routine prenatal care on prevention of preterm labor in patients with a history of preterm labor.

Design

In this pragmatic double-blind, controlled clinical trial, 100 pregnant women with history of preterm labor were assigned into parallel groups using the table of random numbers in a community-based setting.

Settings and conduct

Pregnant women with history of preterm labor at the Imam Khomeini Hospital, Sari, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age higher than 18 years; history of preterm labor. Exclusion criteria: Active labor phase; premature rupture of the fetal membranes; preeclampsia; vaginal bleeding; dilation greater than 3cm and cervical length less than 25mm; intra-amniotic infection; using tocolytic drugs; allergic to progesterone.

Intervention groups

The control group will receive routine prenatal care without any special interventions. The intervention group will receive 250 mg intra-muscular 17 α -Hydroxyprogesterone caproate at 16 weeks of gestation up to 37 weeks of gestation every week.

Main outcome variables

Evaluation and comparison of the mean gestational age at birth, prevalence of preterm labor, and the mean neonatal birth weight in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190309042978N2**

Registration date: **2019-03-19, 1397/12/28**

Registration timing: **prospective**

Last update: **2019-03-19, 1397/12/28**

Update count: **0**

Registration date

2019-03-19, 1397/12/28

Registrant information

Name

Hamed Jafarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

h.jafarpour1@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of 17 α -

Hydroxyprogesterone caproate with routine prenatal care on prevention of preterm labor in patients with a history of preterm labor.

Public title

Effect of 17 α -Hydroxyprogesterone caproate on prevention of preterm labor.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age higher than 18 years History of preterm labor

Exclusion criteria:

Active labor phase Premature rupture of the fetal membranes Preeclampsia Vaginal bleeding Dilation greater than 3cm and cervical length less than 25mm Intra-amniotic infection Using tocolytic drugs Allergic to progesterone

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Totally 100 pregnant women with history of preterm labor at the Imam Khomeini Hospital, Sari, Iran, were chosen. The participants were allocated into groups of intervention and control using the table of random numbers based on computer programs.

Blinding (investigator's opinion)

Double blinded

Blinding description

Pregnant women with history of preterm labor at the Imam Khomeini Hospital, Sari, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Farah Abad Road

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2016-10-18, 1395/07/27

Ethics committee reference number

lr.mazums.imam hospital.rec.96.2741

Health conditions studied

1

Description of health condition studied

Preterm labor

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

Primary outcomes

1

Description

The mean gestational age at birth

Timepoint

After intervention

Method of measurement

Based on the first day of the last menstruation period or ultrasound

2

Description

Prevalence of preterm labor

Timepoint

After intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

The mean neonatal birth weigh

Timepoint

After intervention

Method of measurement

Scale

Intervention groups

1

Description

Intervention group: The intervention group will receive 250 mg intra-muscular 17 α -Hydroxyprogesterone caproate at 16 weeks of gestation up to 37 weeks of gestation every week.

Category

Prevention

2

Description

Control group: The control group will receive routine prenatal care without any special interventions.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Hamed Jafarpour

Street address

Imam Khomeini Hospital, Amir Mazandarani Street

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Email

h.jafarpour@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Saeidi

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Farah Abad Road

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+98 11 3335 2725

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Admission@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Hamed Jafarpour

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome or the like can be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working at science centers and universities

Under which criteria data/document could be used

Our data will be available for scholars working at science centers and universities

From where data/document is obtainable

Hamed Jafarpour provides the data analysis to the applicants via email: h.jafarpour@mazums.ac.ir

What processes are involved for a request to access data/document

Applicants can respond to the email of the respondent and receive a response within a week.

Comments