

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effect of Low-dose aspirin on cervical length as an indicator of preterm delivery in nulliparous pregnant women that has been referred to gynecology clinic in Semnan

Protocol summary

Summary

Objective: the effect of low-dose aspirin on cervical length as an indicator of preterm delivery in nulliparous pregnant women. Design and methods: random (binary random blocks); one center; double-blind; placebo; intervention and control groups. Inclusion criteria: Age between 18 to 40 years; nulliparous; less than 2 miscarriage. Exclusion criteria: history of abortion; contraindication of aspirin usage; smoking and drugs usage; multiple pregnancy; visible fetal anomalies; uterine anomalies. Interventions and main outcome variables: To apply rigorous random assignment, in the first drugs by anyone other than researcher was placed in special packages and packages are labeled with A and B tag. Interventions group: 80 mg of aspirin daily (bedtime) in combination with folic acid + iron tablets from the second trimester will be prescribed to patients and up to 32 weeks of pregnancy to taking medicine. Controls group: Daily folic acid with placebo (Consisting of sugar and starch that the shape, size and color is quite similar to aspirin) + iron tablets will be prescribed to patients. To apply rigorous random assignment, in the first drugs by anyone other than researcher was placed in special packages and packages are labeled with A and B tag. These people will be examined to using the history and physical examination by researchers plan periodically. The cervical length and also blood hemoglobin, once a time at 13 weeks and once again at 30 weeks of pregnancy will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052825732N15**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Low-dose aspirin on cervical length as an indicator of preterm delivery in nulliparous pregnant women that has been referred to gynecology clinic in Semnan

Public title

The effect of Low-dose aspirin on cervical length as an indicator of preterm delivery in nulliparous pregnant women that has been referred to gynecology clinic in Semnan

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 40 years; nulliparous; the singleton pregnancy is between 12 to 13 weeks of pregnancy that is confirmed to medical ultrasound; less than 2 miscarriage in the first 3 months of pregnancy. Exclusion criteria: history of loss pregnancy in second trimester; contraindication of aspirin usage; smoking and drugs usage; multiple pregnancy; visible fetal anomalies by medical ultrasound; hemoglobin level less than 7 milligram per deciliter; previous risk of systemic diseases; individuals with short cervical length less than 25 millimeter; uterine anomalies.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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

Postal code

3514799442

Approval date

2017-05-21, 1396/02/31

Ethics committee reference number

IR.SEMUMS.REC.1396.9

Health conditions studied

1

Description of health condition studied

Preterm labour

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

Primary outcomes

1

Description

Measurement of cervical length

Timepoint

Week 13 and week 30 of pregnancy

Method of measurement

Transvaginal ultrasound

2

Description

Blood hemoglobin

Timepoint

Week 13 and week 30 of pregnancy

Method of measurement

Complete Blood Counter

Secondary outcomes

empty

Intervention groups

1

Description

Interventions group: 80 mg of aspirin daily (bedtime) in combination with folic acid + iron tablets from the second trimester will be prescribed to patients. To apply rigorous random assignment, in the first drugs by anyone other than researcher was placed in special packages and packages are labeled with A and B tag. Participants will start to taking experimental drug and up to 32 weeks of pregnancy (based on medical ultrasound) to continue taking medicine. These people will be examined to using the history and physical examination by researchers plan periodically. The cervical length (using the transvaginal ultrasound method) and also blood hemoglobin (using the complete blood counter in laboratory of Amiralmomenin hospital in Semnan) once a time at 13 weeks and once again at 30 weeks of pregnancy (based on medical ultrasound) will be measured. During periodical examination of pregnancy, the outcome measures are extracted from patients medical records and be recorded in the relevant forms.

Category

Treatment - Drugs

2**Description**

Controls group: Daily folic acid with placebo (Consisting of sugar and starch that the shape, size and color is quite similar to aspirin) + iron tablets will be prescribed to patients.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Gynecology clinic, Amir almoemenin Hospital

Full name of responsible person

Mozhgan Rahmanian

Street address

Amir almoemenin Hospital, Blvd Mostafa Khomeini,
Semnan

City

Semnan

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology,
Semnan University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Asgari

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology, Semnan
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**

Semnan University of Medical Sciences

Full name of responsible person

Mozhgan Rahmanian

Position

Gynecologist

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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