

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Aspirin Effect in the Prevention of Preterm Labor in Patient with Previous Spontaneous Preterm Birth

Protocol summary

Study aim

Aspirin effect in the prevention of preterm labor in patient with previous spontaneous preterm birth

Design

randomized clinical trial with control group, Parallel groups, 190 patient in each group

Settings and conduct

This study will be performed with the participation of pregnant mothers over 18 years of age with singleton pregnancy between 8 to 16 weeks gestation and history of spontaneous preterm birth referred to Mahdiah and Shohada hospitals. Pregnant mothers with inclusion criteria will be randomly divided into intervention and non-intervention groups. All participants' information including demographic information, pregnancy history and maternal illness will be recorded at baseline. After the participants will be assigned to the intervention and non-intervention groups, the intervention group will be given 80 mg daily aspirin tablets produced by Hakim Pharmaceutical Company and the non-intervention group will not be given aspirin. Routine prenatal visits will be made for both groups. Information about pregnancy and childbirth care, including gestational age at delivery, baby weight and Apgar, will be recorded. The data will be collected using a data log checklist.

Participants/Inclusion and exclusion criteria

Singleton pregnancy Gestational age 8-16 weeks
Maternal age upper than 18 years old Previous spontaneous preterm birth

Intervention groups

The intervention group will be given 80 mg daily aspirin tablets produced by Hakim Pharmaceutical Company and the control group will not be given aspirin. Other measures indicated for the prevention of preterm labor in the patient will be performed (from 16 weeks of proleone weekly to 36 weeks, and cerclage if CL > 25). Routine prenatal visits will be made for both groups.

Main outcome variables

Incidence of preterm labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191031045289N1**

Registration date: **2020-02-26, 1398/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-26, 1398/12/07**

Update count: **0**

Registration date

2020-02-26, 1398/12/07

Registrant information

Name

Zahra Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7748 0345

Email address

n.ghaemi.983@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Aspirin Effect in the Prevention of Preterm Labor in Patient with Previous Spontaneous Preterm Birth

Public title

Aspirin Effect in the Prevention of Preterm Labor in Patient with Previous Spontaneous Preterm Birth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton pregnancy Gestational age 8-16 weeks Maternal age upper than 18 years old Previous spontaneous preterm birth

Exclusion criteria:

History of preterm labor due to maternal cause Have other indications of aspirin use Thrombocytopenia Embryonic malformations in this pregnancy or previous preterm pregnancy

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **380**

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant mothers with inclusion criteria will be selected as available sample and then will be randomly divided into intervention and non-intervention groups using random number table.

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 Shahid Beheshti University of Medical Sciences

Street address

No. 115, Teymourifar Ave., Emamat St.

City

Tehran

Province

Tehran

Postal code

1743674181

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.SBMU.MSP.REC.1398.528

Health conditions studied

1

Description of health condition studied

Preterm Birth

ICD-10 code

O60

ICD-10 code description

Preterm labor

Primary outcomes

1

Description

Preterm Labor

Timepoint

Pregnancy termination time

Method of measurement

Gestational age at delivery time

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group will be given 80 mg daily aspirin tablets produced by Hakim Pharmaceutical Company. Routine prenatal visits will be made for this groups. Other measures indicated for the prevention of preterm labor in the patient will be performed (from 16 weeks of proleone weekly to 36 weeks, and cerclage if CL> 25).

Category

Treatment - Drugs

2

Description

Control group: the control group will not be given aspirin. Routine prenatal visits will be made for this groups. Other measures indicated for the prevention of preterm labor in the patient will be performed (from 16 weeks of proleone weekly to 36 weeks, and cerclage if CL> 25).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Masoumeh Mirzamoradi

Street address

Tajrish Sq.

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

Pr_shohada@sbm.ac.ir

2

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Masoumeh Mirzamoradi

Street address

Shishegarkhane Ave., Fadaeian eslam St., Shoush Sq.

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1185817311

Phone

+98 21 5506 2628

Email

mahdiyeh_hospital@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Mirzamoradi

Street address

Arabi St.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

info@sbm.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Dehghani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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n.ghaemi.983@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Dehghani

Position

Resident

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Fax**Email**

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Email

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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

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All participants' information and study results will be shared after anonymity.

When the data will become available and for how long

After printing the results

To whom data/document is available

It will be available to everyone.

Under which criteria data/document could be used

Use of the data is permitted by citing the source.

From where data/document is obtainable

Dr. Zahra Dehghani z.dehghani1367@yahoo.com

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

Contact Dr. Dehghani via the email address provided.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Dehghani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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