

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of taking aspirin in two different diurnal times (morning and night) on mean of 24 hours blood pressure in women who are at preeclampsia risk

Protocol summary

Summary

Objective: to compare the effect of aspirin on blood pressure in two different diurnal times (morning and night) in women at preeclampsia risk. Method: 64 pregnant women randomly assigned to 4 groups. Testing group 1 (100 mg /day aspirin after awakening), testing group2 (100mg/day aspirin at bed time), control group1(placebo after awakening) and control group2 (placebo at bed time). Inclusion criteria: women at higher risk for gestational hypertension and preeclampsia such as women with family history of gestational hypertension and preeclampsia, history of spontaneous abortion, obesity, adolescent or middle age nulliporous pregnancy (less than 18 or more than 35 years). Exclusion criteria: any needs to steroidal or non steroidal or hypertensive drugs, multiple pregnancy, any cardiovascular disease, chronic gastroenteritis and adrenal disease, asthma, hemorrhage disease, diabetes or any other endocrine disease such as hyperthyroidism, hematological disease and intolerance to devise (Ambulatory blood pressure monitoring), abortion, preeclampsia or eclampsia happening in pregnancy, forgetting > 6 tablet in month. The study was started at 12 to16 weeks of gestation and continued until 32 weeks of gestation. Blood pressure was automatically monitored for 24 consecutive hours every 4 weeks from the day of recruitment until delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803211548N5**

Registration date: **2010-02-20, 1388/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

Name

Khadijeh Abdali

Name of organization / entity

Fatemeh college of nursing and midwifery, Shiraz
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4255

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Recruitment status

Recruitment complete

Funding source

Deputy for Research of Shiraz University of Medical
Sciences

Expected recruitment start date

2008-04-12, 1387/01/24

Expected recruitment end date

2008-12-12, 1387/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of taking aspirin in two different diurnal times (morning and night) on mean of 24 hours blood pressure in women who are at preeclampsia risk

Public title

To compare The effect of taking aspirin and placebo in

two different diurnal times (morning and night) on mean of 24 hours blood pressure in women who are at preeclampsia risk

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women with personal and family history of gestational hypertension and preeclampsia, history of spontaneous abortion, obesity, adolescent or middle age nulliporous pregnancy (less than 18 or more than 35 years). Exclusion criteria: using steroidal , non steroidal or antihypertensive drugs, multiple pregnancy, cardiovascular disease, chronic gastroenteritis and adrenal disease, asthma, hemorrhage disease, diabetes or any other endocrine disease ,hyperthyroidism, hematological disease ,intolerance to devise ,Ambulatory blood pressure monitoring.

Age

From **17 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Ethical committee of Shiraz University of medical sciences

Street address

Namazi squer

City

Shiraz

Postal code

Approval date

2008-09-10, 1387/06/20

Ethics committee reference number

87-4227

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

010

ICD-10 code description

Pre-existing hypertension complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

24 hours mean of blood pressure

Timepoint

7 times, every month from the day of recruitment

Method of measurement

24 hour Blood pressure monitoring automatic device

Secondary outcomes

1

Description

preeclampsia prevention and decrease fetal and maternal complications

Timepoint

during and at the end of the pregnancy

Method of measurement

clinically and sonography approved by specialist

Intervention groups

1

Description

testing group 1: aspirin (100mg) at awakening, 1 pill per day

Category

Prevention

2

Description

testing group 2: aspirin (100mg) at bed time, 1 pill per day

Category

Prevention

3

Description

control group 1: placebo at awakening, 1 pill per day

Category

Prevention

4

Description

control group 2: placebo at bed time, 1 pill per day

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez clinic

Full name of responsible person

Dr. Amoe

Street address

Hafez hospital, Abivard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Dabaghmanesh

Street address

Shiraz University of medical sciences, Zand street

City

Shiraz

Grant name

Grant code / Reference number

87-4227

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

Yes

Title of funding source

Deputy for Research of Shiraz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Full name of responsible person

Dr. Amoe

Position

Obstetric and gynecology physician

Other areas of specialty/work

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Hafez hospital, Abivardi

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Khadijeh Abdali

Position

Other areas of specialty/work

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Phone

Fax

Email

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