Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The favorable effects of garlic on metabolic profiles, hs-CRP and biomarkers of oxidative stress in pregnant women at risk for pre-eclampsia

Protocol summary

Summary

Objective: This study is to determine the effects of garlic on metabolic profiles, hs-CRP and biomarkers of oxidative stress in pregnant women at risk for pre-eclampsia. Study design: Randomized double-blind controlled clinical trial. Inclusion and Exclusion Criteria: Pregnant women, primigravida, aged 18-40 year old at 27 weeks' gestation with positive roll-over test will be included in this study. Multiparous women as well as those with hypertension, gestational diabetes mellitus (GDM), complete bed rest (CBR), intra uterine fetal death (IUFD), placenta abruption and preterm delivery will be excluded in the study. Population and sample size: 60 pregnant women of eligible and referred to Kossar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected. Intervention: Patients will be assigned to receive either 400 mg garlic (intervention group: n=30) or placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 9-wk intervention to measure metabolic profiles and biomarkers of oxidative stress. Start and End Date of Intervention: 9 weeks (November 28, 2013-January 7, 2014). Outcomes: Baseline and End-of-trial serum total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides levels, fasting plasma glucose (FPG), plasma total antioxidant capacity (TAC) and total glutathione (GSH).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312125623N15**
Registration date: **2013-12-24, 1392/10/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-24, 1392/10/03

Registrant information

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Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2013-12-02, 1392/09/11

Expected recruitment end date

2014-02-07, 1392/11/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The favorable effects of garlic on metabolic profiles, hs-CRP and biomarkers of oxidative stress in pregnant women at risk for pre-eclampsia

Public title

Effects of garlic in treatment of pregnancy complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant women; primigravida; aged 18-40 year old who were carrying singleton pregnancy at 27 weeks' gestation; positive roll-over test. Exclusion Criteria: Multiparous women; patients with hypertension; gestational diabetes mellitus (GDM); complete bed rest (CBR); intra uterine fetal death (IUFD); placenta abruption; preterm delivery.

Age

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

Gender

Female

Phase

N/A

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

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak

Postal code

Approval date

2013-12-02, 1392/09/11

Ethics committee reference number

92-154-9

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

O94

ICD-10 code description

Sequelae of complication of pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

2

Description

Hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

3

Description

Total Antioxidant Capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

4

Description

Total glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

5

Description

Fasting plasma glucose

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Garlic tablet, daily for 9 weeks

Category

Treatment - Drugs

2

Description
Control group: Placebo tablet, daily for 9 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kossar Clinc
Full name of responsible person
Maryam Karamali
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Maryam Karamali
Street address
Taleghani Hospital, Emam Khomeini Avenue, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Kashan University of Medical Sciences
Full name of responsible person
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Nutrition PhD
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Person responsible for updating data

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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