

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of effects of consumption of probiotic and conventional yogurt on oxidative stress and serum TNF- α and CRP in pregnant women and anthropometric indices of neonates

Protocol summary

Summary

1- Objectives: Previous studies have shown that oxidative stress increases in pregnancy and is associated with several complications of pregnancy. Clinical trials in non-pregnant women have shown that probiotics can decrease oxidative stress. The aim of this study is to determine effects of probiotic yogurt compared to conventional yogurt on oxidative stress and inflammatory markers in pregnant women and anthropometric indices of their neonates. 2- Design: randomized controlled trial 3- Setting and conduct: A hundred healthy pregnant women will be referred from Naghavi Clinic, Kashan University of Medical Sciences. After a 2-week washout period, they will be randomly allocated to receive daily either 200 gram probiotic or conventional yogurt for 9 weeks. Ten milliliters of venous fasting blood sample will be collected at baseline and after intervention. Women will be followed up till delivery. Anthropometric indices of neonates will be measured within the first 24 hours after birth. 4- Participants: healthy pregnant women aged 18-30 years at gestational week 26, Exclusion criteria: premature labor; gestational diabetes or other complications of pregnancy; having illness including cardiovascular, liver or kidney disease 5- Intervention: 200 gram probiotic or conventional yogurt daily for 9 weeks 6- Main outcome measures variables: serum C-reactive protein, glutathione reductase, glutathione peroxidase, 8-oxy-guanine and tumor necrosis factor-alpha, plasma total antioxidant capacity and weight, height and head circumference of neonates

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811282394N3**

Registration date: **2011-06-06, 1390/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2011-06-06, 1390/03/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of consumption of probiotic and

conventional yogurt on oxidative stress and serum TNF- α and CRP in pregnant women and anthropometric indices of neonates

Public title

Effects of consumption of probiotic yogurt in pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria 1- Pregnant women aged 18-30 years; 2- Willing to participate; 3- First pregnancy; Exclusion criteria: 1- Premature labor; 2- Gestational diabetes or other complications of pregnancy; 3- Having illness including cardiovascular , liver or kidney disease

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code**Approval date**

2010-10-10, 1389/07/18

Ethics committee reference number

20402

Health conditions studied**1****Description of health condition studied**

Pregnancy

ICD-10 code

094

ICD-10 code description

Sequelae of complication of pregnancy, childbirth and the puerperium

Primary outcomes**1****Description**

total antioxidant capacity

Timepoint

at baseline, after 9 weeks

Method of measurement

colorimetric

2**Description**

glutathione peroxidase

Timepoint

at baseline, after 9 weeks

Method of measurement

spectrophotometry

3**Description**

glutathione reductase

Timepoint

at baseline, after 9 weeks

Method of measurement

spectrophotometry

4**Description**

8-oxy-guanine

Timepoint

at baseline, after 9 weeks

Method of measurement

ELISA

5**Description**

tumor necrosis factor-alpha

Timepoint

at baseline, after 9 weeks

Method of measurement

ELISA

6**Description**

C-reactive protein

Timepoint

at baseline, after 9 weeks

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

200 gram probiotic yogurt daily at lunch time for 9 weeks

Category

Other

2**Description**

200 gram conventional yogurt daily at lunch time for 9 weeks

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Naghavi Clinic, Kashan University of Medical Sciences

Full name of responsible person

Dr. Samimi

Street address**City**

Kashan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Fotouhi

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Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran.

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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, Tehran 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**

Department of Nutrition, School of public Health, Tehran University of Medical Sciences

Full name of responsible person

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Position

MD, PhD /Assistant Professor

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Web page address**Person responsible for updating data****Contact****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*