Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Name

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Name of organization / entity

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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
spectrophotometery

3

Description
glutathione reductase
Timepoint
at baseline, after 9 weeks
Method of measurement
spectrophotometery

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
Street address
Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran.
City
Tehran
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
Shima Jazayeri
Position
MD, PhD /Assistant Professor
Other areas of specialty/work
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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