

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of effectiveness of multivitamin, multivitamin-mineral supplements, synbiotic and normal Gaz on pregnancy outcomes in pregnant women

Protocol summary

Study aim

Objective: This study is to determine the effects of multivitamin, multivitamin-mineral and synbiotic Gaz supplementation on pregnancy outcomes.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 298 pregnant women of eligible and referred to Naghavi, Shahid Beheshti Clinics, and antenatal centers affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women primigravida, aged 18-35 year old who were carrying singleton pregnancy at their second and third trimester. Exclusion Criteria: Multiparous women, patients with hypertension, gestational diabetes mellitus (GDM), complete bed rest (CBR), intra uterine fetal death (IUFD), placenta abruption, preterm delivery, intrauterine growth restriction (IUGR), history of rheumatoid arthritis, thyroid, parathyroid or adrenal diseases, hepatic or renal failure, hospitalization, signs of malabsorption and maldigestion, metabolic bone disease.

Intervention groups

Intervention: Patients will be assigned to receive either multivitamin-mineral (n=27) or multivitamin (n=27), multivitamin-mineral (n=55) or multivitamin (n=55), multivitamin-mineral (n=39) or multivitamin (n=39), synbiotic Gaz (n=28) or normal Gaz (n=28). Supplements capsules and Gaz are similar in shape and size.

Main outcome variables

Outcomes: Iron, newborns' weight, HDL, insulin and

glutathione (primary outcomes), and insulin metabolism parameters, lipid and metabolic profiles (secondary outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201212105623N3**

Registration date: **2012-12-26, 1391/10/06**

Registration timing: **retrospective**

Last update: **2019-09-28, 1398/07/06**

Update count: **1**

Registration date

2012-12-26, 1391/10/06

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2011-08-10, 1390/05/19

Expected recruitment end date

2012-05-30, 1391/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of multivitamin, multivitamin-mineral supplements, synbiotic and normal Gaz on pregnancy outcomes in pregnant women

Public title

Effects of supplementation in treatment of pregnancy complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women primigravida Aged 18-35 year old who were carrying singleton pregnancy at their second and third trimester

Exclusion criteria:

Multiparous women Patients with hypertension Gestational diabetes mellitus (GDM) Complete bed rest (CBR) Intra uterine fetal death (IUFD) Placenta abruption Preterm delivery Intrauterine growth restriction (IUGR) History of rheumatoid arthritis, thyroid, parathyroid or adrenal diseases Hepatic or renal failure Hospitalization Signs of malabsorption and maldigestion Metabolic bone disease

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **298**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline, after balance randomization, subjects will be divided into groups to take either supplements or control. Intervention group 1: Multivitamin-mineral supplements containing 5000 IU vitamin A, 15 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.7 mg vitamin B2, 20 mg niacin, 2 mg vitamin B6, 400 µg folic acid, 6 µg vitamin B12, 60 mg vitamin C, 125 mg calcium, 18 mg iron, 100 mg magnesium, daily, for 20 weeks. Control group 1: Multivitamin supplements containing 5000 IU vitamin A, 15 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.7 mg vitamin B2, 20 mg niacin, 2 mg vitamin B6, 400 µg folic acid, 6 µg vitamin B12, 60 mg vitamin C, daily, for 20 weeks. Intervention group 2: Synbiotic Gaz containing Lactobacillus sporogenes 107

CFU/g, 0.04 g inulin, 0.38 g isomalt, 0.36 g sorbitol and 0.05 g stevia per 1 g, 9 g, twice a day for 9 weeks.

Control group 2: Normal Gaz, 9 g, twice a day for 9 weeks.

Intervention group 3: Multivitamin-mineral supplements containing 4000 IU vitamin A, 11 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.8 mg vitamin B2, 18 mg niacin, 2.8 mg vitamin B6, 800 µg folic acid, 4 µg vitamin B12, 100 mg vitamin C, 250 mg calcium, 27 mg iron, 25 mg zinc, daily, for 20 weeks. Control group 3: Multivitamin supplements containing 5000 IU vitamin A, 15 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.7 mg vitamin B2, 20 mg niacin, 2 mg vitamin B6, 400 µg folic acid, 6 µg vitamin B12, 60 mg vitamin C, daily, for 20 weeks. Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Approval date

2011-08-09, 1390/05/18

Ethics committee reference number

29/5/1/1384/پ

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

HDL

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

2

Description

Iron

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

3

Description

Total glutathione

Timepoint

Baseline and end-of-trial

Method of measurement

Spectrophotometry

4

Description

Insulin

Timepoint

Baseline and end-of-trial

Method of measurement

Elisa kit

5

Description

Newborns' weight

Timepoint

Delivery time

Method of measurement

Scale

Secondary outcomes

1

Description

Calcium

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

2

Description

Vitamin D

Timepoint

Baseline and end-of-trial

Method of measurement

Elisa kit

3

Description

Magnesium

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

4

Description

Zinc

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

5

Description

Total antioxidant

Timepoint

Baseline and end-of-trial

Method of measurement

Spectrophotometry

6

Description

Newborn's head circumference

Timepoint

The first 24 h after birth

Method of measurement

Tape

7

Description

Newborn's length

Timepoint

The first 24 h after birth

Method of measurement

Tape

8

Description

Apgar score

Timepoint

Delivery time

Method of measurement

Clinical observation

9

Description

Triglycerides

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

10

Description

Cholesterol

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

11

Description

Insulin resistance

Timepoint

Baseline and end-of-trial

Method of measurement

Using HOMA formula

12

Description

VLDL

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

13

Description

LDL

Timepoint

Baseline and end-of-trial

Method of measurement

Enzymatic kit

14

Description

Hs-CRP

Timepoint

Baseline and end-of-trial

Method of measurement

Elisa kit

Intervention groups

1

Description

Intervention group 1: Multivitamin-mineral supplements containing 5000 IU vitamin A, 15 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.7 mg vitamin B2, 20 mg niacin, 2 mg vitamin B6, 400 µg folic acid, 6 µg vitamin B12, 60 mg vitamin C, 125 mg calcium, 18 mg iron, 100 mg magnesium, daily, for 20 weeks.

Category

Treatment - Drugs

2

Description

Control group 1: Multivitamin supplements containing 5000 IU vitamin A, 15 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.7 mg vitamin B2, 20 mg niacin, 2 mg vitamin B6, 400 µg folic acid, 6 µg vitamin B12, 60 mg vitamin C, daily, for 20 weeks.

Category

Treatment - Other

3

Description

Intervention group 2: Synbiotic Gaz containing Lactobacillus sporogenes 107 CFU/g, 0.04 g inulin, 0.38 g isomalt, 0.36 g sorbitol and 0.05 g stevia per 1 g, 9 g, twice a day for 9 weeks.

Category

Treatment - Drugs

4

Description

Control group 2: Normal Gaz, 9 g, twice a day for 9 weeks.

Category

Other

5

Description

Intervention group 3: Multivitamin-mineral supplements containing 4000 IU vitamin A, 11 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.8 mg vitamin B2, 18 mg niacin, 2.8 mg vitamin B6, 800 µg folic acid, 4 µg vitamin B12, 100 mg vitamin C, 250 mg calcium, 27 mg iron, 25 mg zinc, daily, for 20 weeks.

Category

Treatment - Drugs

6

Description

Control group 3: Multivitamin supplements containing 5000 IU vitamin A, 15 IU vitamin E, 400 IU vitamin D3, 1.5 mg vitamin B1, 1.7 mg vitamin B2, 20 mg niacin, 2 mg vitamin B6, 400 µg folic acid, 6 µg vitamin B12, 60 mg vitamin C, daily, for 20 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi gynecology Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaei Avenue, Kashan

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Kashan
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Isfahan
Postal code
81151-87159
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Recruitment center

Name of recruitment center
Shahid Beheshti gynecology clinic
Full name of responsible person
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3

Recruitment center

Name of recruitment center
Antenatal centers
Full name of responsible person
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Phone
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University Of Medical Science
Full name of responsible person
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research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University Of Medical Science

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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Nutrition PhD

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zatollah Asemi

Position

PhD Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available