Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 (secondry 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

Isfehan

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 Rajaee Avenue, Kashan

City
Kashan
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Isfehan
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Phone
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Email
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2

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University Of Medical Science
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Gholamali Hamidi
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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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Full name of responsible person

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Position

Nutrition PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address

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

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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