Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of low Trans Fatty Acid content diet on adverse pregnancy outcomes

Protocol summary

Study aim

Effect of low trans-fatty acid intakes during pregnancy on adverse pregnancy outcomes

Design

A randomized controlled clinical trial with an intervention group, without blinding, on 800 pregnant women. Latin randomization and Excel software were used for randomization. The intervention group with the received food pattern with the content of trans fatty acids less than 1% and the control group with the received food pattern without change in the content of trans fatty acids.

Settings and conduct

This clinical trial study was performed in health centers affiliated to Shahid Beheshti University of Medical Sciences. For pregnant women in intervention group was designed to have a trans fatty acid intake of less than 1%, but this change was not observed in the diet of pregnant women in the control group. No blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with normal pregnancy and gestational age less than 8 weeks
Exclusion criteria: Pregnant women with chronic disease with a history of preeclampsia, gestational diabetes and low birth weight baby

Intervention groups

Women in intervention group received individualized dietary pattern with trans fatty acids content under 1% of total daily energy intake, and in the control group, women received individualized dietary pattern without any focus on trans fatty acids content. Women in control group received individualized dietary pattern without any change in trans fatty acids content.

Main outcome variables

Preeclampsia Gestational diabetes mellitus Low birth weight

General information

Reason for update

The reason for the update is to extract the results of this clinical trial. This study showed that a diet low in trans fatty acids can reduce the incidence of gestational diabetes, low birth weight and preeclampsia. Of the 800 women (n=407 in control and n=393 in intervention groups), 108 (13.5%) women were diagnosed with low birth weight. The incidence of low birth weight in intervention group was 12% and in control group was 19%. After multivariable adjustment for confounders, the hazard ratios for incident low birth weight in intervention group were 0.65 (0.44-0.96). Kaplan-Meier plot showed significant difference between two groups in incidence of low birth weight. There were statistically significant differences in intakes of daily trans fatty acids between the groups ($P < 0.05$). The hazard ratio (95% CI) for the incidence of preeclampsia in the intervention group was 0.56 (0.33–0.93). 14 women in the intervention group (5%) and 31 women in the control group (8%) were diagnosed with gestational diabetes mellitus. Chi-square test did not show any significant difference between two groups (P=0.08). Cox model was used and the variables were examined in four multivariate models that none of the modals showed a statistically significant difference between the two groups regarding the incidence of GDM.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092729902N3**
Registration date: **2016-11-08, 1395/08/18**
Registration timing: **retrospective**

Last update: **2020-12-07, 1399/09/17**
Update count: **1**

Registration date

2016-11-08, 1395/08/18

Registrant information

Name

Seideh Hanieh Alamolhoda

Name of organization / entity
Shahid Beheshti University Of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
common project between Nursing and Midwifery Faculty with Endocrine and Metabolism Research Center of Shahid Beheshti University Of Medical Sciences

Expected recruitment start date
2014-09-23, 1393/07/01
Expected recruitment end date
2016-07-22, 1395/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of low Trans Fatty Acid content diet on adverse pregnancy outcomes

Public title
The effect of low trans fatty acid diet on adverse pregnancy outcomes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged 18-35 years. Pregnant women who are less than 7 weeks pregnant. Pregnant women with singleton pregnancies. Pre pregnancy body mass index 19-25 kg/m2 Pregnant women who have a pre-pregnancy body mass index of 19-25 kg / m2. Pregnant women who are literate.
Exclusion criteria:
Diagnose fetal abnormalities in the current pregnancy. Pregnant women with severe nausea and vomiting during pregnancy. Pregnant women who smoke. Pregnant women who drink alcohol. Pregnant women who are addicted to drugs.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **800**
Randomization (investigator's opinion)
Randomized
Randomization description
Intervention (dietary pattern with trans fatty acids<1%) and control through blocked randomization in block sizes of four and six and with an allocation ratio of 1:1. To conceal the allocation, the type of intervention (dietary pattern with trans fatty acids<1% or routine diet) was written on paper and placed into sequentially numbered opaque envelopes. The researcher opened the envelopes sequentially when a participant entered into the study, and, depending on the type of group written on the paper in the envelope, the participants were allocated to the relevant group. Blocking was done by a person not involved in the sampling.
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 Shahid Beheshti University Of Medical Sciences
Street address
Shahid Beheshti University Of Medical Sciences, Velenjak, Tehran
City
Tehran
Province
Tehran
Postal code
1155673970
Approval date
2016-05-17, 1395/02/28
Ethics committee reference number
IR.SBMU.ries.Rec.1394.92

Health conditions studied

1

Description of health condition studied
preeclampsia
ICD-10 code
O14
ICD-10 code description
Pre-eclampsia

2

Description of health condition studied

Low birth weight

ICD-10 code

P05.18

ICD-10 code description

Newborn small for gestational age, 2000-2499 grams

3

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description

Preeclampsia

Timepoint

28 weeks of pregnancy

Method of measurement

Midwifery questionnaire

Secondary outcomes

1

Description

Gestational diabetes

Timepoint

28 weeks of pregnancy

Method of measurement

Midwifery questionnaire

2

Description

Low birth weight

Timepoint

At birth time

Method of measurement

Measurement with weight of Mark Seka

Intervention groups

1

Description

Intervention group: Women in intervention group received individualized dietary pattern with trans fatty acids content under 1% of total daily energy intake. we replaced mono- and polyunsaturated fatty acids with free of trans fatty acids in dietary pattern, such as olive oil, fish, nuts, and low fat (1.5%) dairy products, and participants were forbidden to consume the food rich of trans fatty acids such as any kind of fast foods, processed meat, and deep fried foods.

Category

Prevention

2

Description

women received individualized dietary pattern without any focus on trans fatty acid content. women were allowed to consume any kind of dairy products and oil for cooking and routine dietary recommendation were advised.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Seideh Hanieh Alamolhoda

Street address

Taleghani Hospital, Velenjak, Tehran

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Tehran

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Tehran

Postal code

1155673970

Phone

+98 21 8820 2512

Email

alamolhoda.h@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor Of Research, Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

Street address

Shahid Beheshti University Of Medical Sciences, Velenjak, Tehran

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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 Of Research, Shahid Beheshti University Of Medical Sciences

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

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Seideh Hanieh Alamolhoda

Position

Faculty Member of Nursing and Midwifery Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nursing and Midwifery Faculty, Valiasr street and Niayesh highway junction

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Email

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Seideh Hanieh Alamolhoda

Position

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Person responsible for updating data

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Position

Faculty Member of Nursing and Midwifery Faculty

Latest degree

Master

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Low trans fatty acid and gestational diabetes mellitus Low trans fatty acid and preeclampsia Low trans fatty acid and low birth weight

When the data will become available and for how

long

2018

To whom data/document is available

Public

Under which criteria data/document could be used

No criteria need

From where data/document is obtainable

Physicians Midwifes Health care giver

What processes are involved for a request to access data/document

No processes need

Comments