

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Determining the effectiveness of interventional plan of care diet and physical activities on pregnancy outcomes in pregnant women with metabolic syndrome

Protocol summary

Summary

This double-blind clinical trial aims to determine the effect of physical activity and diet on the outcome of pregnancy among 122 pregnant women with metabolic syndrome who are referred to Ayatullah Rouhani Center for pregnancy care in the first trimester of pregnancy. The IDF scale is used to diagnose metabolic syndrome. Women with 3 out of 5 signs (based on BP, weight, height, W.C., HDL, TG, FBS before intervention) will be included in the study. Also written consent should be obtained from patients. Patients will be randomly divided into two groups using a computerized program. The intervention group receives the physical activity program three one-hour sessions a week in combination with Mediterranean diet with key components including high intake of fruit and vegetables, non-refined grains, legumes, moderate to high consumption of fish, small to moderate intake of poultry and dairy products such as yoghurt and cheese, low consumption of red meat and processed meat and avoidance of sugary drinks, fast food and food rich in animal fat until the end of pregnancy. The control group will receive routine pregnancy care until the end of pregnancy. After the end of pregnancy, The maternal (pre-eclampsia, Gestational Diabetes, Extreme weight gain during pregnancy, Pregnancy-induced hypertension) and neonatal (Preterm labor, Apgar Score, IUGR, LGA) outcomes of pregnancy will be measured among two groups using a questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042333070N1**

Registration date: **2017-10-04, 1396/07/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-04, 1396/07/12

Registrant information

Name

Farideh Mohsenzadeh - ledari

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

f.ledari@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Sharoud University of Medical Sciences

Expected recruitment start date

2017-09-21, 1396/06/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effectiveness of interventional plan of care diet and physical activities on pregnancy outcomes in pregnant women with metabolic syndrome

Public title

The Effect of Diet and Physical Activities on Pregnancy

Complications in Metabolic Syndrome

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria: Women with metabolic disorders; gestational age less than 14 weeks; able to read and write in Persian; respond to questionnaire without the help of another person; signing the consent to participate in the research project; have no visual or auditory disorder; mental illness does not require medication or continuous psychiatrist's care; not having any underlying diseases. Exclusion criteria: pregnant women who do not wish to participate in the study.

Age
From **14 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **122**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Shahroud University of Medical Sciences

Street address
Shahroud University of Medical Sciences, Hafte-Tir Square, Shahroud

City
Shahroud

Postal code
36147-73947

Approval date
2016-11-09, 1395/08/19

Ethics committee reference number
IR.SHMU.REC.1395.123

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
Pre-eclampsia

Timepoint
The end of intervention

Method of measurement
Checklist;Clinical signs;test;Measuring Blood Pressure

2

Description
Gestational Diabetes

Timepoint
The end of intervention

Method of measurement
Fasting Blood Sugar;blood sugar 2 hours after eating

3

Description
Pregnancy-induced hypertension (PIH)

Timepoint
The end of intervention

Method of measurement
Measuring Blood Pressure

4

Description
Excessive Weight Gain During Pregnancy

Timepoint
During and at the end of the intervention

Method of measurement
Weight Measurement

Secondary outcomes

1

Description
Preterm labor

Timepoint
During and at the end of the intervention

Method of measurement
Gestational age by obstetric ultrasonography.

2

Description
Macrosomia

Timepoint

During and at the end of the intervention

Method of measurement

Measure of weight Infant

3

Description

Intra uterine growth restriction

Timepoint

During and at the end of the intervention

Method of measurement

Evaluation of gestational age based on ultrasound fetal growth measurements

4

Description

Apgar score

Timepoint

End of intervention

Method of measurement

Determination of Apgar score at five scale Apgar

Intervention groups

1

Description

The intervention group will receive a designed care plan including one-hour Physical activity sessions, three times a week and Mediterranean diet after the 14th week of pregnancy. The key components of the diet will include high intake of fruit and vegetables, non-refined grains, legumes, moderate to high fish consumption, low to moderate intake of poultry and dairy products such as yoghurt and cheese, low consumption of red meat and processed meat and avoidance of sugary drinks, fast food and food rich in animal fat which are delivered to the patients through brochures and training CD in addition to standard care during pregnancy.

Category

Lifestyle

2

Description

The control group received the standard prenatal

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Farideh Mohsenzadeh Ledari

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Emamiyan

Street address

Shahroud University of Medical Sciences,Haft-Tir Square,Shahroud

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Zahra Mottaghi

Position

PhD reproductive health

Other areas of specialty/work

Street address

Shahroud University of Medical Sciences,Haft-Tir Square,Shahroud.

City

Shahroud

Postal code

Phone

+98 23 3239 5054

Fax

Email

zharmotaghi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Nursing and

Midwifery Care Research Center, Iran University of
Medi

Full name of responsible person

Ziba Taghizadeh

Position

PhD reproductive health

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Vali Asr
street,Tehran

City

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Fax

Email

zibataghizadeh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Farideh Mohsenzadeh Ledari

Position

PhD candidate in reproductive health

Other areas of specialty/work

Street address

Shahroud University of Medical Sciences, Hafte-Tir
Square,Shahroud

City

Shahroud

Postal code

36147-73947

Phone

+98 23 3239 5054

Fax

+98 911 119 2989

Email

Mohsenzadh2008@gmail.com

Web page address

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