Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The study of the effectiveness rate of nutrition education on the basis of Pender's model on weight gaining pattern and some of its outcome in pregnant women and their babies.

Protocol summary

Summary

Intra uterine nutrition is very important because heart diseases ,diabetes(type 2),and hyper lipidemia and many other complications in adolescents are related to fetal period.On the other hand, pregnancy has shown to be an independent risk factor for developing over weight. So we determined the effectiveness rate of nutrition education on the basis of pender's model on weight gaining pattern and some of it's outcome (determination and comparison of mother weight gaining pattern, energy and macro nutrients intake, mean blood pressure, and fast blood sugar and serum insulin in both the intervention and control group before and after intervention and birth weight, birth head, birth length. Also, infant weight, length, and head).Also Pender 's health promotion model components score before and after intervention will be determined. Expected outcomes: We hope to modify macro and micro nutrients intake, healthy nutrition habits, weight gaining pattern(in each BMI groups).We will consider fetus and infant growth (weight, length, and head) too. Nutrition educational sessions include of 210 individuals and 400 groups. Anthropometric indexes in 6-10, 18, 26, 35 weeks in pregnancy and 8-26 weeks post partum were collected. 72 hr recall, physical activity questionnaire, and Pender's questionnaire before and after of intervention were filled. Nutrition education (independent variable) include of correct nutritional principles in pregnancy, maternal nutrition portions, individual calorie calculation. Dependent variables are pregnancy gained weight, blood pressure in 2nd half of pregnancy, fasting blood glucose and insulin. First outcome in baby is birth weight, height, and head circumference. Maternal second outcome is gained weight in 8 and 26 weeks post partum. Primiparous 19-40 years, mentally and physically health with single fetus who their pregnancies ended to alive and healthy baby included to survey.

Exclusion criteria are weight related, medical complications, diabetes mellitus, chronic diseases, addiction, special regimen related complications, and BMI>35.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012026129N1**
Registration date: **2016-05-18, 1395/02/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-18, 1395/02/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The study of the effectiveness rate of nutrition education on the basis of Pender's model on weight gaining pattern and some of its outcome in pregnant women and their babies.

Public title
The effectiveness of nutrition education in prediction of pregnancy obesity
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: 19-40 years old pregnant women; single pregnancy; alive child birth; apparently healthy; mentally healthy; primipara women. Exclusion criteria: medical complication related to weight gaining; insulin dependent diabetes; drug dependent hypertension; overt diabetes; psychiatric and mental diseases; addiction; nutrition related diseases; chronic diseases; renal diseases; anemia; special complications related to diets; BMI >35; gastro- intestinal complication and hyper emesis gravidarum.
Age
From **19 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
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
Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences, Shahid Sadoughi blvd., Bahonar Sq.
City
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Postal code
8916978477
Approval date
2016-05-01, 1395/02/12
Ethics committee reference number
IR.SSU.SPH.REC.1395.13

2

Ethics committee
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Postal code
Approval date
2015-06-02, 1394/03/12
Ethics committee reference number
17/48268/پ

Health conditions studied

1

Description of health condition studied
Obesity in pregnancy
ICD-10 code
E66
ICD-10 code description
Obesity

Primary outcomes

1

Description
Pregnancy weight gaining
Timepoint
At trimesters of pregnancy, at the end of pregnancy
Method of measurement
Weight measurement

2

Description
Fasting blood sugar and fasting insulin
Timepoint
At 12th and 34th week of pregnancy
Method of measurement
Blood sampling

Secondary outcomes

1

Description
birth height
Timepoint
at the end of pregnancy (birth time)
Method of measurement
meter

2

Description
Post partum weight
Timepoint
Six month after pregnancy
Method of measurement
Weight measurement

3

Description
Birth weight
Timepoint
At the end of pregnancy (birth time)
Method of measurement
Weight measurement

4

Description
head circumference
Timepoint
at the end of pregnancy (birth time)
Method of measurement
meter

Intervention groups

1

Description
control group intervention include of simple nutritional education which presented by midwives or obstetricians for pregnant mother.
Category
Other

2

Description
interventional nutrition education include of correct nutritional principles in pregnancy, intake portions of food groups, necessary calorie for pregnant mother considering carbohydrate, protein, and fat percent base of Pender's models.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Prenatal care centers in health centers and hospitals and private offices
Full name of responsible person
Street address
City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Amir Houshang Mehrparvar
Street address
Shahid Sadoughi University of Medical Sciences, Building No. 2, Shahid Sadoughi blvd., Bahonar Sq.
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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
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Person responsible for scientific inquiries

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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