Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of 8 wks Yoga training on serum levels of Vaspin, insulin resistance and blood glucose in pregnant women with Gestational diabetes mellitus

Protocol summary

Study aim

The effect of eight wks Yoga training on serum levels of Vaspin, insulin resistance and blood glucose in pregnant women with Gestational diabetes mellitus

Design

All mothers with gestational diabetes who are referred to the Prenatal Clinic of Hafez Hospital, affiliated to Shiraz University of Medical Sciences, are selected to receive health care. Sampling will be carried out voluntarily and out of available individuals. A sample of 30 non pregnant women with gestational age of 24 weeks and gestational diabetes mellitus (GDM), one hour glucose monitoring (OGTT) test, with 50 grams of glucose, was used to diagnose gestational diabetes.

Settings and conduct

The experimental group performed yoga exercises for eight weeks and five sessions per week, with three sessions a week with a mentor in the gymnasium of Hafez clinic and two sessions per week at home. Practice protocol includes Yoga Asana and Yoga Pranayama.

Participants/Inclusion and exclusion criteria

inclusion criteria: All pregnant women with gestational diabetes and gestational age between 24 -30 wks have fasting blood glucose less than 105 mg / L and blood glucose less than 120 mg / dL. Exclusion criteria: pregnant women with cardiovascular disease, kidney and liver problems, pulmonary disease, or orthopedic restrictions and preeclampsia

Intervention groups

In this study, intervention group will perform the yoga practice for eight weeks and five sessions per week for one hour. The exercise protocol includes 21 moves from Asana and Pranayama Yoga. The experimental group will also receive standard diabetes care. The control group will receive only standard diabetes care during these eight weeks and will not do yoga exercises.

Main outcome variables

The percentage of pregnant women with fasting blood glucose is less than 105 mg / L and blood glucose is below 120 mg / dL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140317017035N4**
Registration date: **2018-04-18, 1397/01/29**
Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date

2018-04-18, 1397/01/29

Registrant information

Name

Maryam Kasraeian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-06-06, 1397/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 wks Yoga training on serum levels of Vaspin, insulin resistance and blood glucose in pregnant women with Gestational diabetes mellitus

Public title

Effect of Yoga training in Gestational diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with Gestational diabetes mellitus Gestational age between 24 -30 weeks Fasting blood glucose less than 105 mg / L and blood glucose less than 120 mg / dL.

Exclusion criteria:

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

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 Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Province

Fars

Postal code

14336IR.SUMS.REC.139

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.SUMS.REC.1396.164

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

Primary outcomes

1

Description

The percentage of pregnant women with fasting blood glucose is less than 105 mg / L and blood glucose is below 120.

Timepoint

The subjects' blood sugar levels will be measured 24 hours before the training protocol and 48 hours after the end of the protocol.

Method of measurement

Measurement of serum glucose by glucose oxidase (Pars Test, Iran)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group will perform the yoga practice for 8 weeks and five sessions per week for one hour. The exercise protocol includes 21 moves from Asana and Pranayama Yoga. The experimental group will also receive standard diabetes care.

Category

Treatment - Other

2

Description

Control group: The control group will receive only standard diabetes care during these eight weeks and will not do yoga exercises.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez Clinic of Shiraz University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
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Fatemeh Sarikhani
Position
MSC of Physilology exercise
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
IPD: Information and research data Ethic form: Complete the Ethic form by the patient
When the data will become available and for how long
IPD: 2018 Ethic form: 2018
To whom data/document is available
IPD: Researcher & Patient Ethic form: Patient
Under which criteria data/document could be used
IPD: Ethic form: Awareness of test results
From where data/document is obtainable
IPD: OB & Gyn ward Shiraz university of medical sciences Ethic form: OB & Gyn ward Shiraz university of medical sciences
What processes are involved for a request to access data/document
IPD: Vice chancellery Ethic form: Vice chancellery
Comments