

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 23 32365

##### Email address

kasraeem@sums.ac.ir

##### 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**

Fatemeh Sarikhani

**Street address**

Shahid Chamran blvd, Hafez Clinic

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**Postal code**

34786-71946

**Phone**

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fatimasarikhani38@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shiraz University Of medical Science

**Street address**

Building of Shiraz University of Medical Sciences,  
Zand Ave

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hashemib@sums.ac.ir

**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

**Full name of responsible person**

Fatemeh Sarikhani

**Position**

MSC of Physilology exercise

**Latest degree**

Master

**Other areas of specialty/work**

Others

**Street address**

Department of obstetrics and gynecology, Shahid  
Faghihi Hospital, Zand St, Shiraz, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Kasraeian

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Khadijeh Bazrafshan

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Human Ecology

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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**