

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of eight weeks of aquatic training on metabolic factors, body composition, sleep quality and back pain in pregnant women with gestational diabetes mellitus

Protocol summary

Study aim

Gestational diabetes is a common complication of pregnancy in which hyperglycemia occurs spontaneously during pregnancy. The importance of sports activities is being studied by researchers. Studies have shown that physical activity in pregnancy has effective physiological and metabolic effects and improves insulin resistance. Therefore, in the present study, the effect of performing sports activities in water on body composition and glycemic indices was investigated.

Design

The research design is practical and is done with a pre-test-post-test design that will last for eight weeks. As a sample, 30 people are selected according to the criteria for entering the research. Then, they are randomly divided into two groups of training in water and control. The water training program is three sessions a week and the control group follow their daily activities. Body composition indices and blood samples are taken before and after the implementation of the plan.

Settings and conduct

Isfahan University-Faculty of Sports Sciences

Participants/Inclusion and exclusion criteria

All of them should have general health and their gestational diabetes should be confirmed by a doctor. All participants must be between the ages of 20 and 40. All participants followed a special diet. All participants did not participate in sports activities during the last six months. All participants do not have a history of premature birth. All participants do not need prenatal care. Absent more than 2 to 5 training sessions alternately during the training period. Musculoskeletal injury occurs during the exercise program. Use other sports supplements.

Intervention groups

Aqua training group Control group

Main outcome variables

Body weight Body mass index Fat percentage Fasting glucose Blood insulin Insulin resistance Glycosylated hemoglobin Sleep quality Back pain Pain in the pelvic girdle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230920059475N1**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **retrospective**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

Shahla Lessani

Name of organization / entity

The University of Esfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of aquatic training on metabolic factors, body composition, sleep quality and back pain in pregnant women with gestinal diabetes mellitus

Public title

The effect of eight weeks of aquatic training on metabolic factors, body composition, sleep quality and back pain in pregnant women with gestinal diabetes mellitus

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

They all have general health and their gestational diabetes will be confirmed by a doctor. All participants are between the ages of 20 and 40. All participants follow their normal diet. All participants have not participated in sports activities in the last six months. All participants do not have a history of premature birth. All participants do not need prenatal care.

Exclusion criteria:

Absent more than 2 to 5 training sessions alternately during the training period. Musculoskeletal injury occurs during the exercise program Use other sports supplements.

Age

From **20 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)

Randomized

Randomization description

Simple randomization The samples will be determined by the random block method with 4-blocks and using the random numbers table of Allocation Random software. Blocking and allocation sequence for concealment will be done by a person not involved in the research.

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**

National Committee on Ethics in Biomedical Research

Street address

Central Building of Ministry of Health and Medical Education, simaye iran street, Qods Township (West), Tehran, Iran

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Tehran

Province

Tehran

Postal code

1111111111

Approval date

2023-09-26, 1402/07/04

Ethics committee reference number

59475

Health conditions studied**1****Description of health condition studied**

Gestational Diabetes

ICD-10 code

024.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes**1****Description**

Weight measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

Using SECA scales made in Germany.

2**Description**

Body mass index measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

Height to weight ratio

3**Description**

Fat percent measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

Body composition device

4

Description

Fasting blood glucose measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

Blood sampling is taken by expert in laboratory.

5

Description

Blood insulin measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

Blood sampling is taken by expert in laboratory.

6

Description

Insulin resistance measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

Blood sampling is taken by expert in laboratory.

7

Description

Measurement of glycosylated hemoglobin

Timepoint

It is measured before and after eight weeks.

Method of measurement

Blood sampling is taken by expert in laboratory.

8

Description

Measurement of sleep quality

Timepoint

It is measured before and after eight weeks.

Method of measurement

Pittsburgh Sleep Quality Questionnaire

9

Description

Back pain measurement

Timepoint

It is measured before and after eight weeks.

Method of measurement

OSWESTRY DISABILITY INDEX Questionnaire

10

Description

Measurement of pelvic girdle pain

Timepoint

It is measured before and after eight weeks.

Method of measurement

Pelvic Girdle Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: There are three sessions per week of the training program in the water, which lasts for 75 minutes. The exercise program is carried out under the supervision of a hydrotherapy specialist.

Category

Other

2

Description

Control group: They do not have any sports activities and only do daily activities.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan university

Full name of responsible person

Shahla Lessani

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Faculty of Sports Sciences - Isfahan University - Hazarjarib Street - Isfahan City - Isfahan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Isfahan

Full name of responsible person

Hadi Amiri

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Faculty of Sports Sciences - Isfahan University - Hezar Jarib Street - Isfahan City - Isfahan Province

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

The University of Isfahan

Proportion provided by this source

50

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**

The University of Isfahan

Full name of responsible person

Mehdi Kargari Fard

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Physiology

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Usage data is shared after being de-identified.

When the data will become available and for how long

The access period starts 6 months after the publication of the results

To whom data/document is available

Community members, clinical experts and sports science researchers

Under which criteria data/document could be used

The results obtained using statistical analysis show the

effectiveness of the exercise program and only pregnant women with diabetes are allowed to use this exercise protocol.

From where data/document is obtainable

Researcher (Shahla Lasani) Isfahan, Isfahan University, Faculty of Sports Sciences Corresponding author (Mehdi Kargari Fardi), Isfahan University, Faculty of Sports Sciences

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

The implementation of the research design lasts for 10 weeks, the first and tenth weeks are related to the measurement of the study variables, and the exercise program is eight weeks, with three sessions per week.

Comments