Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

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
City
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
Street address
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
Street address
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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Person responsible for updating data

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Full name of responsible person
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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