

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of eight weeks of aquatic exercise on body composition, blood lipids and thyroid hormone levels in pregnant women

Protocol summary

Study aim

The effect of aquatic exercise on body composition, blood lipids and thyroid hormone levels in pregnant women.

Design

The clinical trial with a randomized control group, on 30 patients, was used for randomization using the block of six method.

Settings and conduct

The samples were selected from health centers in Isfahan city. The intervention group starts training in water from 20 to 34 weeks of pregnancy. People in the intervention group during pregnancy perform water sports with moderate intensity 3 times a week for 40 minutes in the indoor pool of Isfahan University under the supervision of a trainer and a midwife. The control group will receive usual pregnancy care and no exercise intervention. A researcher-made questionnaire will be used to measure pregnancy outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria at 20-34 weeks of pregnancy and consent to participate in the study. Exclusion criteria: diseases such as: blood pressure, heart problems, absence of more than 2 sessions in sports programs, lack of satisfaction with participating in the research.

Intervention groups

The intervention group starts exercise from 20-34 weeks of pregnancy and they do aquatic exercise in the indoor swimming pool of Isfahan University under the supervision of a trainer and midwife during pregnancy. The control group will receive routine care during pregnancy and will not have exercise intervention.

Main outcome variables

Body composition, blood lipids and thyroid hormone levels in pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230819059185N1**

Registration date: **2023-09-24, 1402/07/02**

Registration timing: **prospective**

Last update: **2023-09-24, 1402/07/02**

Update count: **0**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Nastaran Motavali

Name of organization / entity

The university of Esfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 4536 4231

Email address

motavalinb199@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-30, 1402/08/08

Expected recruitment end date

2023-11-29, 1402/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of aquatic exercise on body composition, blood lipids and thyroid hormone levels in

pregnant women

Public title
The effect of aquatic exercise in water on thyroid hormone

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
20-34 weeks of pregnancy Consent to participate in the study
Exclusion criteria:
Diseases such as: blood pressure, heart problems, absence of more than 2 sessions in exercise programs Dissatisfaction with participating in the research

Age
From **25 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **15**
Blood fat levels, body composition and thyroid hormone.

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization will be in the form of six-block randomization. The current research will be conducted as a clinical trial. Pregnant women will be randomly assigned to the intervention and control groups using blocks of six. The research environment will be Isfahan University.

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
Ethical Committee of Isfahan University
Street address
University of Isfahan, Azadi Square
City
Esfahan
Province

Isfahan
Postal code
817467344
Approval date
2023-08-14, 1402/05/23
Ethics committee reference number
IR.UI.REC.1402.058

Health conditions studied

1

Description of health condition studied
Thyroid hormone, blood lipid levels, body composition
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Body composition
Timepoint
Before the start of the intervention and 8 weeks after the intervention
Method of measurement
Body composition analysis device

2

Description
Blood lipid levels
Timepoint
Before the start of the intervention and 8 weeks after the intervention
Method of measurement
Serum measurement

3

Description
Thyroid hormone
Timepoint
Before the start of the intervention and 8 weeks after the intervention
Method of measurement
Serum measurement

Secondary outcomes

empty

Intervention groups

1

Description
The number of people in the intervention group is 15 people. The intervention group starts training from 20 to 34 weeks of pregnancy. People in the intervention group during pregnancy perform water sports for 8 weeks, 3

sessions a week and each session is 40 minutes with moderate intensity in the indoor swimming pool of Isfahan University under the supervision of a trainer and a midwife. The time of each session includes: impact position, warm-up phase (5 minutes), aerobic phase (20 minutes), strength phase (10 minutes) and the last final phase of returning to the relaxation state (5 minutes) in which relaxation techniques and Muscles are stretched.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Deputy Health Center, Kamal St

Full name of responsible person

Mehdi Kargarfard

Street address

Isfahan Azadi Square, University of Isfahan, Faculty of Sport Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3668 7572

Fax

+98 31 3668 7571

Email

m.kargarfard@spr.ui.ac.ir

Web page address

<https://spr.ui.ac.ir/m.kargarfard>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Faculty of Sports Sciences and Physical Education, University of Isfahan

Full name of responsible person

Isfahan University Research Assistant

Street address

University of Esfahan, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3793 2571

Fax

+98 31 3793 2572

Email

m.kargarfard@spr.ui.ac.ir

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

Yes

Title of funding source

Faculty of Sports Sciences and Physical Education, University of Isfahan

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**

The university of Isfahan

Full name of responsible person

Mehdi Kargarfard

Position

Faculty at University of Isfahan

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

Mehdi Kargarfard Professor, University of Isfahan
Faculty of Sport Sciences Department of Exercise
Physiology Hezar Jerib Street, P.O. Box 81746-7344
Ph: +98 31 37934282 Fax: +98 31 36687572 Email:
m.kargarfard@spr.ui.ac.ir

City

Isfahan

Province

Isfahan

Postal code

81746-7344

Phone

+98 31 3668 7572

Fax

+98 31 3668 7572

Email

m.kargarfard@spr.ac.ir

Web page address

<https://spr.ui.ac.ir/m.kargarfard>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Kargarfad

Position

Faculty at University

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

Mehdi Kargarfad Professor, University of Isfahan
Faculty of Sport Sciences Department of Exercise
Physiology Hezar Jerib Street, P.O. Box 81746-7344
Ph: +98 31 37934282 Fax: +98 31 36687572 Email:
m.kargarfad@spr.ui.ac.ir

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۴۱

Phone

+98 31 3668 7572

Fax

+98 31 3668 7396

Email

m.kargarfad@spr.ui.ac.ir

Web page address

<https://spr.ui.ac.ir/m.kargarfad>

Person responsible for updating data

Contact

Name of organization / entity

The university of Esfahan

Full name of responsible person

Nastaran Motavali

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

Street address

University of Esfahan, Azadi Square, Esfahan

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۴۱

Phone

+98 31 3793 2128

Fax

+98 31 3668 7396

Email

m.kargarfad@spr.ui.ac.ir

Web page address

<https://spr.ui.ac.ir/m.kargarfad>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available