

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

study of The effect of physical activity in water on musculoskeletal pain in pregnant women

Protocol summary

Study aim

To examine the effect of physical activity in water on the amount of musculoskeletal pain in pregnant women referring to Qazvin health centers

Design

Clinical trial with intervention and control group (each group of 30), community based and pragmatic, with parallel, randomized block

Settings and conduct

60 pregnant women who has the conditions to enter the study is available and after completing the checklist for demographic and pregnancy information and Nordic musculoskeletal pain questionnaire, Roland Morris's back pain and visual analogue and Confirmation of Musculoskeletal pain will be entered into the study with written consent, then the samples will be randomly divided into intervention and control groups. In the intervention group, receiving usual care during pregnancy, physical activity in water 3 times per week and 60 minutes each time for 8 The week will be performed by a trained researcher at the pool and in the control group just the usual care with You will receive.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The desire to participate in the study
Having musculoskeletal pain Not having chronic illness
Gestational age is 20-23 weeks Exclusion criteria:
Exercise contraindication in pregnancy Having a mental illness Fear of water

Intervention groups

Intervention group: In the intervention groups, in addition to the usual prenatal cares, Participate in the water physical activity program, 3 times a week for 8 weeks. The sessions were composed of three phases: warming up exercises; the main phase (divided into aerobic exercise and force and resistance exercise) and a phase of stretching and relaxation. Control group: They were received the usual prenatal care.

Main outcome variables

Musculoskeletal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190130042565N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Masomeh Rezai niaraki

Name of organization / entity

The Collage of Nursing and Midwifery Qazvin

Country

Iran (Islamic Republic of)

Phone

+98 28 3377 4522

Email address

m.rezainiaraki@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study of The effect of physical activity in water on musculoskeletal pain in pregnant women

Public title

Effect of water activity on musculoskeletal pain in pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having musculoskeletal pain Not having chronic diseases (blood pressure, diabetes, cardiovascular disease, etc.) Not having known musculoskeletal disorders based on mother's statement Gestational age 23-20 weeks

Exclusion criteria:

Having a contraindication for exercise during pregnancy Having mental illness Fear of water

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

60 low risk pregnant women selected by a convenience sampling method. They were selected and by the block randomization technique assigned into intervention and control groups (two groups n=30).

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 Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2019-01-08, 1397/10/18

Ethics committee reference number

IR.QUMS.REC.1397.284

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

Musculoskeletal pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

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

Musculoskeletal pain in pregnant women

Timepoint

Before and after intervention

Method of measurement

Nordic musculoskeletal pain inventory, Roland Maurice Low Back Pussy Questionnaire, Visual Analogue

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention groups, in addition to the usual prenatal cares, Participate in the water physical activity program, 3 times a week for 8 weeks. The sessions were composed of three phases: warming up exercises; the main phase (divided into aerobic exercise and force and resistance exercise) and a phase of stretching and relaxation.

Category

N/A

2**Description**

Control group: They were received the usual prenatal care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Qazvin city

Full name of responsible person

Fatemeh Ranjkesh

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Qazvin university of medical sciences, Bahonar Blvd.,
Qazvin city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Fatemeh Ranjkesh

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research.dpt@qums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Fatemeh Ranjkesh

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All the data have code to identify.

When the data will become available and for how long

2019

To whom data/document is available

Qazvin University of Medical Sciences

Under which criteria data/document could be used

By confirmation of Qazvin University of Medical Sciences

From where data/document is obtainable

Qazvin University of Medical Sciences

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

Refer to Qazvin University of Medical Sciences or sending email to franjkesh@qums.ac.ir

Comments