Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of a cycle of exercises on pregnancy outcomes in Primigravida Women

Protocol summary

Summary

Investigation of the effect of a cycle of exercises on pregnancy outcomes Objectives:the present study aims to determine the relationship between exercising and pregnancy outcomes Design: this stady is a clinical trial and The randomization was done in the draw that The method of sampling was simple sample into two groups. Setting and conduct: in this stady 120 pregnant women were randomly divided into an intervention and a control group Major Inclusion criteria:primiparous ;18-35 years old; gestational age of 20 weeks ; singleton pregnancy ; being primiparous; not having the history of pregnancy complications; not having the history of doing professional sports; and normal Body Mass Index (BMI=20-25) Exclusion criteria: were suffering from underlying diseases; women’s or pregnancy disorders; having known pregnancy complications; having limitations for doing physical activities; and not being willing to participate in the study. Intervention: The intervention group participants were required to do aerobic exercises for 8 weeks since the 20th week of gestation in addition to receiving the routine care. However, the control group mothers only received the routine pregnancy care main outcome measures (variables): Then pregnancy outcomes; such as length of pregnancy; delivery phases; type of delivery; and infants’ physiological indexes; such as Apgar score ; weight; height; and head circumference were measuring.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403167497N3**
Registration date: **2016-02-18, 1394/11/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-18, 1394/11/29

Registrant information

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Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of a cycle of exercises on pregnancy outcomes in Primigravida Women

Public title

the effect of cycle of exercises on pregnancy outcomes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: primiparous ;18-35 years old; gestational age of 20 weeks ; singleton pregnancy ; being primiparous; not having the history of pregnancy complications; not having the history of doing professional sports; and normal Body Mass Index (BMI=20-25) Exclusion criteria: were suffering from underlying diseases; such as hypertension ; thyroid disorders; women’s or pregnancy disorders; diabetes; epilepsy;cardiovascular diseases; renal disorders; and pulmonary diseases; having known pregnancy complications; such as polyhydramnios; oligohydramnios; placenta previa;detachment; known fetal disorders; intrauterine death; cervical insufficiency;history of infertility; bleeding during pregnancy; and pain; having limitations for doing physical activities; and not being willing to participate in the study. .

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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
Zand street, Shiraz University of Medical Sciences, Shiraz

City
Shiraz

Postal code

Approval date
2015-11-21, 1394/08/30

Ethics committee reference number
IR.SUMS.REC.1394.151

Health conditions studied

1

Description of health condition studied
delivery

ICD-10 code
O80

ICD-10 code description
Single spontaneous delivery

2

Description of health condition studied
delivery

ICD-10 code
O82

ICD-10 code description
Single delivery by caesarean section

3

Description of health condition studied
delivery

ICD-10 code
O81

ICD-10 code description
Single delivery by forceps and vacuum extractor

4

Description of health condition studied
delivery

ICD-10 code
O83

ICD-10 code description
Other assisted single delivery

Primary outcomes

1

Description
duration of pregnancy

Timepoint
After delivery

Method of measurement
Chart

2

Description
type of delivery

Timepoint
after intervention

Method of measurement
chart

3

Description
apgar scor

Timepoint

after intervention
Method of measurement
Chart

4

Description
back pain
Timepoint
after intervention
Method of measurement
visual scale of pain

Secondary outcomes

1

Description
Assess back pain
Timepoint
The begain of intervention and after intervention
Method of measurement
the 10 point Visual Analog Scale (VAS)

Intervention groups

1

Description
The intervention group subjects were required to do aerobic exercises 30 minutes a day, three days a week for 8 weeks. Aerobic exercise program started with 5 minutes warming, continued with the main plan which usually lasted for 20 minutes, and ended with cooling for 5 minutes. These exercises were strictly supervised by the instructor and the midwife. In each session, 10 types of aerobic exercises were performed, including warming for 5 minutes, stretching exercises, and cooling for 5 minutes. The intensity of exercises was controlled by measuring the participants' heartbeat; such a way that their heartbeat would not exceed 140 beats per minute (bpm) the control group mothers only received the routine pregnancy care
Category
Behavior

2

Description
The control group participants, on the other hand, only received the routine care without performing aerobic exercises.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Zinabieh hospital ,zinabieh street , shiraz
Full name of responsible person
Monireh Toosi
Street address
Shiraz University of Medical Sciences, shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr.seyed basier hashemi
Street address
Zand street, Shiraz University of Medical Sciences , shiraz
City
Shiraz
Grant name
9401859123
Grant code / Reference number
Ir.sums.rec.1394.151
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty