Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Hormonal, Lactate, and Cardiac Autonomic Responses to Resistance Exercise with and Without Blood Flow Restriction at Menstrual Cycle Phases in Trained Women

Protocol summary

Study aim

Investigating the effect of resistance exercise (with and without blood flow restriction) in different phases of menstrual cycle

Design

The study will be conducted using a cross-over design on one group of participants and two types of resistance exercises (with and without blood flow restriction), in follicular and luteal phases of menstrual cycle, on 12 trained women

Settings and conduct

This study will be conducted in the University of Guilan sports physiology laboratory. participants will perform 4 sessions of resistance exercises (2 sessions of traditional resistance exercise with 70%1RM and 2 sessions of resistance exercise with blood flow restriction and 30%1RM with 60% of limb occlusion pressure, in two consecutive menstrual cycles in luteal and follicular phases. Blood samples will be collected before and after the exercise.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Trained women with at least six months of regular resistance training experience, Regular menstrual cycles (28–32 days) and Range of age between 20 to 30 years; Exclusion criteria: Taking hormonal medications or oral contraceptives during the past six months, Consumption of nutritional supplements or caffeine at least 48 hours prior to testing and The history of cardiovascular, metabolic, endocrine, or neurological diseases

Intervention groups

Each participant completes two intervention conditions: resistance exercise without blood flow restriction at 70% of one-repetition maximum (leg press and knee extension; 4×10 with 1-minute rest) and resistance exercise with blood flow restriction at 30% of one-repetition maximum (at 60% limb occlusion pressure; the same exercises in four sets: 30 repetitions in the first set and three sets of 15 repetitions with 1-minute rest).

Main outcome variables

Growth hormone, Cortisol, Blood Lactate, Heart Rate Variability, Rating of Perceived Exertion (RPE)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251202068190N1**
Registration date: **2026-04-11, 1405/01/22**
Registration timing: **retrospective**

Last update: **2026-04-11, 1405/01/22**
Update count: **0**

Registration date

2026-04-11, 1405/01/22

Registrant information

Name

Zahra Aftabi Talami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-17, 1404/03/27

Expected recruitment end date

2025-07-30, 1404/05/08

Actual recruitment start date
2025-06-17, 1404/03/27
Actual recruitment end date
2025-07-27, 1404/05/05
Trial completion date
2025-07-27, 1404/05/05

Scientific title
Hormonal, Lactate, and Cardiac Autonomic Responses to Resistance Exercise with and Without Blood Flow Restriction at Menstrual Cycle Phases in Trained Women

Public title
The effect of resistance exercise with and without blood flow restriction during different phases of the menstrual cycle in trained women
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Trained women with at least six months of regular resistance training experience Regular menstrual cycles (28–32 days) Range of age between 20 to 30 years
Exclusion criteria:
Taking hormonal medications or oral contraceptives during the past six months Consumption of nutritional supplements or caffeine at least 48 hours prior to testing The history of cardiovascular, metabolic, endocrine, or neurological diseases
Age
From **20 years** old to **30 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **12**
More than 1 sample in each individual
Number of samples in each individual: **8**
Pre and post test blood samples in Traditional Resistance Exercise in the luteal phase, Traditional Resistance Exercise in the follicular phase, Resistance Exercise with Blood Flow Restriction in the luteal phase and Resistance Exercise with Blood Flow Restriction in the follicular phase. (one group of participants will perform 4 sessions of exercise and the samples will be measured before and after each session; pre-post test)
Actual sample size reached: **12**
More than 1 sample in each individual
Actual sample size in each individual: **8**
Pre and post test blood samples in Traditional Resistance Exercise in the luteal phase, Traditional Resistance Exercise in the follicular phase, Resistance Exercise with Blood Flow Restriction in the luteal phase and Resistance Exercise with Blood Flow Restriction in the follicular phase. (one group of participants will perform 4 sessions of exercise and the samples will be measured before and after each session; pre-post test)
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Guilan
Street address
University of Guilan, 5th Kilometer of Rasht-Qazvin road, Rasht, Guilan province, Iran
City
Rasht
Province
Guilan
Postal code
4199613776
Approval date
2025-04-14, 1404/01/25
Ethics committee reference number
IR.GUILAN.REC.1404.019

Health conditions studied

1

Description of health condition studied
Menstrual cycle status
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Growth hormone
Timepoint
Pre-test (before the exercise session) and post-test (after the test/end of the exercise session)
Method of measurement
Serum growth hormone concentration will be measured through blood sampling and laboratory assessment using the Enzyme-Linked Immunosorbent Assay (ELISA) method.

2

Description

Cortisol

Timepoint

Pre-test (before the exercise session) and post-test (after the test/end of the exercise session).

Method of measurement

Serum cortisol concentration will be measured using blood sampling and laboratory analysis by the enzyme-linked immunosorbent assay (Enzyme-Linked Immunosorbent Assay).

3

Description

Blood Lactate

Timepoint

Pre-test (before the exercise session) and post-test (after the test/end of the exercise session).

Method of measurement

Plasma lactate level will be measured using blood sampling and laboratory analysis by a standard enzymatic method.

4

Description

Heart Rate Variability

Timepoint

Heart rate variability will be recorded and analyzed in 5-minute time windows during the pre-test period and immediately after the test.

Method of measurement

Heart rate variability will be measured and analyzed using a Polar H10 heart rate sensor.

Secondary outcomes

1

Description

Blood Pressure

Timepoint

Pre-test (before the exercise session) and post-test up to 60 minutes after the test.

Method of measurement

By using Sphygmomanometer

2

Description

Rating of Perceived Exertion (RPE)

Timepoint

Immediately after completion of each set of the exercise

Method of measurement

By using the Borg rating of perceived exertion scale

Intervention groups

1

Description

Control group: Resistance exercise without Blood Flow Restriction; Participants will perform traditional resistance exercise at an intensity of 70% of one-repetition maximum (1RM). The training protocol will include of two exercises, leg press and leg extension, each will be performed for 4 sets of 10 repetitions. Rest intervals will consist of 1 minute between sets and 2-3 minutes between two exercises. The intervention will be conducted over two consecutive menstrual cycles, such that one session will be performed during the follicular phase and one session during the luteal phase.

Category

Diagnosis

2

Description

Intervention group: Resistance exercise with Blood Flow Restriction (BFR); Participants in this group will perform resistance exercises (leg press and leg extension) at an intensity of 30% of 1RM. BFR will be applied using a cuff placed at the proximal portion of the lower limb, with a pressure set at 60% of Limb Occlusion Pressure (LOP). The training protocol will consist of 4 sets (30-15-15-15 repetition), with one minute of rest between sets and 2-3 minutes between two exercises. The intervention will be conducted over two consecutive menstrual cycles, such that one session will be performed during the follicular phase and one session during the luteal phase.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Guilan

Full name of responsible person

Javad Mehrabani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Guilan

Full name of responsible person

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Grant name

Grant code / Reference number

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

Title of funding source
University of Guilan

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
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Full name of responsible person
Zahra Aftabi Talami
Position
Student
Latest degree
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Other areas of specialty/work
Exercise Physiology
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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

Yes - There is a plan to make this available

Title and more details about the data/document

This document includes a complete description of the study design, training protocol, intervention schedule, measurement methods for all variables, and study procedures, prepared to enhance transparency and reproducibility of the results.

When the data will become available and for how long

After publication of the study results

To whom data/document is available

Researchers and the academic staff

Under which criteria data/document could be used

The data are available solely for research purposes, subject to confidentiality requirements and approval by the principal investigator.

From where data/document is obtainable

Through the principal investigator.

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

Email of the principal investigator

Comments