

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 13 3360 1360

##### Email address

zahraaftabi.t@gmail.com

##### 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

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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

#### **Street address**

University of Guilan, 5th Kilometer of Rasht-Qazvin road, Rasht, Guilan province, Iran

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#### **Province**

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mehrabanij@guilan.ac.ir

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

University of Guilan

#### **Full name of responsible person**

Ali Bani

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bani@guilan.ac.ir

**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**

University of Guilan

**Full name of responsible person**

Zahra Aftabi Talami

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

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

University of Guilan

**Full name of responsible person**

Javad Mehrabani

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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University of Guilan

**Full name of responsible person**

Zahra Aftabi Talami

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

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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**