

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Balneotherapy on Body Mass Index, Adipokine Levels, Sleep Disturbances and Quality of Life of Women with Morbid Obesity

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of balneotherapy on body mass index, adipokine levels, sleep quality and quality of life in morbidly obese female patients.

##### Design

50 morbid obese female patients will be studied. Body mass indexes and waist / hip ratios will be calculated. With Skinfoldmeter the subcutaneous fat thickness will be measured and the fat tissue percentage will be calculated. The Pittsburgh Sleep Quality Index (PUKI) will be used to assess sleep quality and the Nottingham Health Profile (NSP) will be used to assess quality of life. In addition to routine biochemical tests, leptin, adipokine, visfatin, and cortisol from the saliva sample will be studied from the blood sample. All assessments will be performed both before and after treatment. A total of 15 sessions of 20 minutes of spa treatment will be administered 5 days a week.

##### Settings and conduct

It will be a non-randomized clinical trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: \*Morbidly obesity (BMI greater than 40 kg/m<sup>2</sup>) women aged between 18-70 Exclusion criteria: \*Uncontrolled hypertension, diabetes, coronary artery disease etc systemic diseases \*Systemic infections \*Malignancy \*Pregnancy and/or lactation \*Debility \*Bleeding diathesis \*Psychological pathologies

##### Intervention groups

Patients will receive 15 sessions of spa treatment. Changes in some clinical and laboratory values before and after treatment will be assessed.

##### Main outcome variables

Body mass index Waist to hip ratio Total fat percent (according to skinfoldmeter measurements) Sleep quality Quality of life Routine blood biochemistry Eritrocyte sedimentation ratio, C-reactive protein, fibrinogene levels in blood Adipokine (adiponectin, leptin, visfatin) levels in blood

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180108038268N1**

Registration date: **2018-02-03, 1396/11/14**

Registration timing: **prospective**

Last update: **2018-02-03, 1396/11/14**

Update count: **0**

##### Registration date

2018-02-03, 1396/11/14

##### Registrant information

##### Name

Fatmanur Aybala Koçak

##### Name of organization / entity

Ahi Evran University Faculty of Medicine

##### Country

Turkey

##### Phone

+90 386 213 45 15

##### Email address

aybala.kocak@ahievran.edu.tr

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-15, 1396/11/26

##### Expected recruitment end date

2018-03-15, 1396/12/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Effect of Balneotherapy on Body Mass Index, Adipokine Levels, Sleep Disturbances and Quality of Life of Women with Morbid Obesity

## Public title

Balneotherapy Treatment for Obesity

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Morbidly obesity (BMI greater than 40 kg/m<sup>2</sup>) Women  
Aged between 18-70

### Exclusion criteria:

Uncontrolled hypertension, diabetes, coronary artery disease etc systemic diseases Systemic infections  
Malignancy Pregnancy and/or lactation Debility Bleeding diathesis Severe psychological pathologies

## Age

From **18 years** old to **70 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Turgut Özal University

##### Street address

Çamlıca Mh., Anadolu Blv

##### City

Ankara

##### Postal code

06560

#### Approval date

2015-10-08, 1394/07/16

#### Ethics committee reference number

99950669/205

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

Body mass index, waist to hip ratio, total fat percent (according to skinfoldmeter measurements) sleep quality, quality of life, routine blood biochemistry, eritrocyte sedimentation ratio, C-reactive protein, fibrinogene, adipokines (adiponectin, leptin, visfatin) levels in blood.

#### Timepoint

Before intervention, after 15 sessions of balneotherapy (after 3 weeks)

#### Method of measurement

Tape measure, weigher, skinfoldmeter, laboratory tests

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahi Evran University, Faculty of Medicine

##### Full name of responsible person

Fatmanur Aybala Koçak

##### Street address

Bağbaşı Mah, Şehit Sahir Kurutluoğlu Cad., No:100

##### City

Kırşehir

##### Postal code

40200

##### Phone

+90 386 215 45 15

##### Email

aybala.kocak@ahievran.edu.tr

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahi Evran University Scientific Research Projects  
Coordination Unit

**Full name of responsible person**

Fatmanur Aybala Koçak

**Street address**

Bağbaşı Mah. Şehir Sahir Kurutluoğlu Cad. No:100

**City**

Kırşehir

**Postal code**

40200

**Phone**

+90 386 213 45 15

**Email**

aybala.kocak@ahievran.edu.tr

**Grant name**

Ahi Evran University Scientific Research Projects  
Coordination Unit.

**Grant code / Reference number**

TIP.A3.16.006

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

Yes

**Title of funding source**

Ahi Evran University Scientific Research Projects  
Coordination Unit

**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**

Ahi Evran University

**Full name of responsible person**

Fatmanur Aybala Koçak

**Position**

Asist. Prof.

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Bağbaşı Mah. , Şehir Sahir Kurutluoğlu Cad., No:100

**City**

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**Province**

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**Postal code**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahi Evran University

**Full name of responsible person**

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## Person responsible for updating data

### Contact

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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

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

all collected data will be shared

### When the data will become available and for how long

starting 10 months after publication

### To whom data/document is available

people working in academic institutions

### Under which criteria data/document could be used

only for academic purposes

### From where data/document is obtainable

via e-mail: aybala.kocak@ahievran.edu.tr

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

via e-mail: aybala.kocak@ahievran.edu.tr

### Comments