

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of the effect of nettle (*urtica dioica*) extract on medical parameters and insulin resistance in pediatric patients with obesity

#### Protocol summary

##### Study aim

Investigating the effect of nettle extract on metabolic parameters and insulin resistance in obese children

##### Design

The clinical trial has a control group, with parallel groups, a blind strain, randomized, on 64 patients, and SAS version 9 software is used for randomization with 4 permuted block randomization method.

##### Settings and conduct

The study will be conducted in 17 Shahrivar hospital (endocrine department) in two intervention and control groups. The patients are not blind to the treatment group and are only researchers and statistics experts analyzing the information blind to the treatment group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 12 to 18 years old BMI greater than 85th percentile for age and sex Lack of sensitivity to nettle and its products (if exposed and reported by the patient) Not suffering from hypotension (lower blood pressure less than 90 on 60 mm Hg) Absence of heart and kidney failure (according to medical examinations and laboratory results) Exit criteria: The patient's unwillingness to participate in the study Patient taking lithium, warfarin and antihypertensive drugs Fluid retention due to reduced heart and kidney function

##### Intervention groups

The first group receives 5 cc of nettle syrup twice a day along with the diet, and the second group follows the diet alone. The duration of the intervention is 12 weeks and all patients are monitored weekly and monthly by pediatric endocrinologists.

##### Main outcome variables

Fasting blood sugar, fasting blood insulin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220516054879N3**

Registration date: **2022-12-25, 1401/10/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-12-25, 1401/10/04**

Update count: **0**

##### Registration date

2022-12-25, 1401/10/04

##### Registrant information

###### Name

maryam shahrokhi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3336 9026

###### Email address

mshahrokhi@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-04-21, 1402/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of nettle (*urtica dioica*) extract on medical parameters and insulin resistance in pediatric patients with obesity

##### Public title

effect of nettle extract on insulin resistance

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children 12 to 18 years old BMI greater than 85th percentile for age and sex Allergy to nettle and its products (if exposed and reported by the patient) Not suffering from hypotension (lower blood pressure less than 90 on 60 mm Hg) Absence of heart and kidney failure (according to medical examinations and laboratory results)  
**Exclusion criteria:**  
patient reluctance to participate in the study, Patient taking lithium, warfarin and antihypertensive drugs, Fluid retention due to reduced heart and kidney function

**Age**  
From **12 years** old to **18 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Type of randomization, details of any restrictions (such as blocking and block size): Permuted block randomization method of 4 is used to randomize people in two groups. Considering that group A is the intervention group and group B is the control group.The randomization process will be as follows. The entire randomization file is available as an Excel file (randomization was done with SAS software version 9) The method used to generate a random allocation sequence by mentioning the name of the software or site used: Randomization was done with SAS software version 9 Allocation concealment method: Group assignment will be done through closed envelopes. Randomization implementation process: The randomization process will be carried out under the supervision of the project manager and by him and with the direct supervision of the statistician and the supervisor.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Since it is not possible to make a placebo for us due to the taste and smell of the product; One group of patients receives nettle syrup in addition to following the diet, and in the other group, only the diet is controlled. Therefore, the patients are not blinded to the treatment group, and they are only researchers and statistical experts analyzing the information blinded to the treatment group.

**Placebo**

Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Gilan University of Medical Sciences  
**Street address**  
Rasht-Namjo Street-Shahid Siadati Street-in front of 17 Shahrivar Hospital-Deputy for Research and Technology  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4193713111

**Approval date**  
2022-12-07, 1401/09/16

**Ethics committee reference number**  
IR.GUMS.REC.1401.458

**Health conditions studied**

**1**

**Description of health condition studied**  
Insulin resistance - obesity - children

**ICD-10 code**  
E66

**ICD-10 code description**  
Overweight and obesity

**Primary outcomes**

**1**

**Description**  
fasting blood suger

**Timepoint**  
month 0, 1, 3

**Method of measurement**  
blood test

**2**

**Description**  
Fasting insulin levels

**Timepoint**  
month 0, 1, 3

**Method of measurement**  
blood test

### 3

#### Description

Homa insulin resistance factor

#### Timepoint

month 0, 1, 3

#### Method of measurement

blood test

### Secondary outcomes

empty

### Intervention groups

#### 1

#### Description

Intervention group: In addition to following the diet, nettle syrup (hydroalcoholic extract) of Zarband company is received in the form of 5 cc twice a day for 12 weeks.

#### Category

Treatment - Other

#### 2

#### Description

Control group: the diet alone is observed for 12 weeks

#### Category

Lifestyle

### Recruitment centers

#### 1

#### Recruitment center

##### Name of recruitment center

17 shahrivar hospital

##### Full name of responsible person

Maryam Shahrokhi

##### Street address

Rasht - Namjo Street - Shahid Siyadati Street - 17 Shahrivar Hospital

##### City

Rasht

##### Province

Guilan

##### Postal code

4144654379

##### Phone

+98 13 3336 9019

##### Email

17shahrivar@gums.ac.ir

### Sponsors / Funding sources

#### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

Mohammadreza Naghipour

#### Street address

Rasht - Namjo Street - Shahid Siyadati Street - in front of 17 Shahrivar Hospital

#### City

Rasht

#### Province

Guilan

#### Postal code

4193713111

#### Phone

+98 13 3333 6394

#### Email

research@gums.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Rasht 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

Rasht University of Medical Sciences

##### Full name of responsible person

Maryam Shahrokhi

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Rasht - Namjo Street - Shahid Siyadati Street - 17 Shahrivar Hospital

##### City

Rasht

##### Province

Guilan

##### Postal code

414465379

##### Phone

0098133369019

##### Email

shahrokhi.mail85@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Maryam Shahrokhi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Rasht - Namjo Street - Shahid Siyadati Street - 17  
Shahrivar Hospital

**City**

Rasht

**Province**

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**Postal code**

4144654379

**Phone**

+98 13 3336 9019

**Email**

shahrokhi.mail85@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Zahra Khalatbari

**Position**

Pharmacy student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Rasht - Hafez Street - Ghalamestan 3 - Ali Building

**City**

Rasht

**Province**

Guilan

**Postal code**

4145695715

**Phone**

+98 901 533 0905

**Email**

zahrakhalatbari6@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Preservation of patients' privacy and compliance with ethical principles

**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**

No - There is not 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**

The results of the study will be available to everyone.

Exclusive information will be available only to the treatment staff. To respect the privacy of the patient, the patient's information will be kept by the researcher.

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

Currently, there is no plan to publish the data, but if it is published, it will be 6 months after the results are published.

**To whom data/document is available**

Researchers who are active in this field, pediatric specialists and scientific and qualified people

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

Doctors and researchers will have the right to request, there are restrictions in order to protect the patient's privacy and comply with medical ethics

**From where data/document is obtainable**

17 Shahrivar Hospital, Rasht - Dr. Maryam Shahrokhi, Faculty of Pharmacy, Gilan Medical Sciences - Zahra Khalatbari

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

Go to 17 Shahrivar Hospital in Rasht and sign the application form, then meet with the researcher of the plan and review the application of the referring person, consult with the ethics committee in medicine and then submit the documents.

**Comments**