

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the effect of extract of nettle (*Urtica Dioica*) on blood glucose in adolescent patients with type 1 diabetes , A Randomized Double Blinded Controlled Trial

Protocol summary

Study aim

Due to that the major human studies performed in patients with type 2 diabetes, as well as the limited human studies and different results of previous studies, this study will be conducted to investigate the effect of nettle extract on blood sugar control and insulin dose in patients with type 1 diabetes.

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, on 50 patients and the <https://www.sealedenvelope.com> website is used for randomization.

Settings and conduct

Will be performed in 17 Shahrivar Hospital of Rasht. (Endocrinology Department) The study will be conducted in two groups of intervention and control. Researchers, and data analysts will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 12-18 years old Patients with type 1 diabetes treated with insulin and with improper blood sugar control (A1C greater than 6.5 mg / dl) provided that their BUN and serum creatinine are satisfactory and the patient does not classified as a patient with renal impairment.(BUN 8-20 mg / dL and creatinine less than 1.5 mg / dL.) Exclusion criteria: Patient disinclination Patient taking lithium, warfarin and antihypertensive drugs due to drug interactions according to who source History of previous allergies to nettle edible products Changes more than 0.3 units in patient renal function parameters

Intervention groups

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

Main outcome variables

Fasting blood sugar, A1C

General information

Reason for update

Regarding the insufficient cooperation of children, using placebo was impossible.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054879N2**

Registration date: **2022-07-06, 1401/04/15**

Registration timing: **prospective**

Last update: **2023-03-08, 1401/12/17**

Update count: **1**

Registration date

2022-07-06, 1401/04/15

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

2022-07-23, 1401/05/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of extract of nettle (*Urtica Dioica*) on blood glucose in adolescent patients with type 1 diabetes , A Randomized Double Blinded Controlled Trial

Public title

Evaluation of the effect of extract of nettle (*Urtica Dioica*) on blood glucose in adolescent patients with type 1 diabetes , A Randomized Double Blinded Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

12-18 years old Patients with type 1 diabetes treated with insulin and with improper blood sugar control (A1C greater than 6.5 mg / dl) provided that their BUN and serum creatinine are satisfactory and the patient does not classified as a patient with renal impairment.(BUN 8-20 mg / dL and creatinine less than 1.5 mg / dL.)

Exclusion criteria:

Patient reluctance Patient taking lithium, warfarin and antihypertensive drugs Due to the existence of drug interactions according to the WHO source History of previous allergies to nettle edible products Change of more than 0.3 units in the parameters of patient's renal function

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type, details of any restrictions (such as blocking and block size): Due to the equality and lack of diagnosis of the type of treatment by the participants, the block randomization method will be used. According to the number of sample sizes, the size of the blocks is 4. The method used to generate a random allocation sequence using the name of the software or site used: Random blocking will be assigned to research units in numbers 1 to 30, respectively. Then a table with 6 rows called blocks and each block will have 5 sections and each section will be named with A and B, will be considered. In the next step, the numbers are placed in each house in order. After all the numbers are placed in the blocks, the people who had the number in house A will receive the intervention medicine and the people

who had the number in house B will be considered as the control group. The website <https://www.sealedenvelope.com> is used for randomization. Allocation Concealment method: The numbered Sequentially Envelopes: sealed, opaque envelopes method is used to hide random allocation. Randomization process (who will determine the random allocation sequence, who will register participants, who will assign participants to interventions): The randomization process will be performed under the supervision of the project manager and by him and with the direct supervision of a statistician and the supervisor.

Blinding (investigator's opinion)

Double blinded

Blinding description

the investigator and data analyzer were blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of guilan university of medical sciences

Street address

Dputy of research and technology, In front of 17 shahrivar hospital, Shaid siadati street, Namjoo street, Rasht

City

Rasht

Province

Guilan

Postal code

4193713111

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.GUMS.REC.1401.113

Health conditions studied**1****Description of health condition studied**

Type 1 diabetes - insulin - children

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

fasting blood glucose sugar reduction

Timepoint

The variable will be measured at the beginning of the study, 4, 8 and 12 weeks after the start of the study.

Method of measurement

Home glucose testing devices or blood tests

Secondary outcomes

1

Description

A1C reduction

Timepoint

This variable will be measured at the beginning of the study and 12 weeks after the start of the study.

Method of measurement

blood test

2

Description

Insulin dose reduction

Timepoint

This variable will be measured at the beginning of the study and 12 weeks after the start of the study.

Method of measurement

blood test

Intervention groups

1

Description

Intervention group received insulin with 5 cc of zardband company nettle syrup (Hydroalcoholic extract) twice a day for 12 weeks.

Category

Treatment - Other

2

Description

Control group received routine insulin

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

17 shahrivar hospital

Full name of responsible person

Maryam Shahrokhi

Street address

17shahrivar hospital - SHahid siadati street - Namjoo street - Rasht

City

Rasht

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4144654379

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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

In front of 17 shahrivar Hospital-Shahid Siadati Street-Namjoo Street-Rasht

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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

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

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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

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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Reyhaneh Haghghi

Position

Pharmacy student

Latest degree

Medical doctor

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Medical Pharmacy

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reyhaneh.haghghi76@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

Patient privacy and 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, specific information will be available only to the treatment staff. To protect the patient's privacy, the patient's information will be protected by the researcher.

When the data will become available and for how long

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

To whom data/document is available

Researchers working in this field - pediatricians and scientists with qualifications

Under which criteria data/document could be used

Physicians and researchers will have the right to request, there are restrictions on patient privacy and medical ethics

From where data/document is obtainable

Dr. Maryam Shahrokhi-17 Shahrivar Hospital, Rasht
Reyhaneh Haghghi - School of Pharmacy guilan university of meical science

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

Refer to the 17 Shahrivar Hospital in Rasht and sign the application form, then meet with the project researcher and review the client's request - consult with the Medical Ethics Committee, then provide documentation

Comments