Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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
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
In front of 17 shahrivar Hospital-Shahid Siadati Street-Namjoo Street-Rasht
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?
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
Street address
17shahrivar Hospital-Shahid Siadati Street-Namjoo Street-Rasht
City
Rasht
Province
Guilan
Postal code
414465379
Phone
+98 13 3336 9019
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
17shahrivar Hospital-Shahid Siadati Street-Namjoo Street- Rasht
City
Rasht
Province
Guilan
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
Reyhaneh Haghghi
Position
Pharmacy student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
3rd floor-Farrokhi Building-Emadieh Alley-Gas square towards lakan-Rasht
City
Rasht
Province
Guilan
Postal code
4145695715
Phone
+98 911 380 3496
Email
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 Haghi - 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