Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Urtica Dioica leaves extract on glycemic control in patients with type 1 diabetes mellitus

Protocol summary

Summary

This study evaluates the effect of Urtica Dioica leaves extract on glycemic control in patients with type 1 diabetes mellitus and is adouble blind clinical trial with participation of 64 children with type I diabetes mellitus, referred to endocrine clinic of Gorgan Taleghani hospital.Those patients who meet the inclusion criteria, after Obtaining informed consent, will be enrolled in the study. After obtaining HgA1C level and other necessary laboratory tests, the patients will randomly assign to either the intervention group or the control group (32 patients per group). In the intervention group nettle extract in form of capsules will be given at dose of 100 mg/m2 and the control group will receive placebo at same dose for 3 months, along with their usual dose of insulin. During the study, patients will be followed with phone calls and frequent visits. At the end of 3 months, HgA1C and other laboratory tests will be repeated and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412084585N7**
Registration date: **2015-03-03, 1393/12/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-03, 1393/12/12

Registrant information

Name
Maryam Razzaghy-Azar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6694 2903
Email address
mrazar@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Golestan University of Medical sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Urtica Dioica leaves extract on glycemic control in patients with type 1 diabetes mellitus

Public title

Effect of Nettle extract on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :diagnosis of T1DM based on ADA criteria; at least 6 months have passed since diagnosis of diabetes; age 6 to 16 years; no other underlying disease
Exclusion criteria :inappropriate use of nettle; Parents lack the necessary cooperation and regular visits; diagnosis of other disease during study period; drug intolerance or occurrence of side effects necessitating drug discontinuation; use of other drugs such as herbal formulas or complementary vitamins

Age

From **6 years** old to **16 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Golestan University of Medical Sciences
Street address
Falsafi educational department, Shast kola avenue
City
Gorgan
Postal code
Approval date
2014-09-02, 1393/06/11
Ethics committee reference number
1479179306197

Health conditions studied

1

Description of health condition studied
Diabetes Mellitus
ICD-10 code
E10
ICD-10 code description
Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HbA1C
Timepoint
3 Months
Method of measurement
percent of glycosylated hemoglobin

Secondary outcomes

1

Description
Insulin
Timepoint
3 Months
Method of measurement
Units of insulin

Intervention groups

1

Description
For intervention group nettle capsules with dose of 100mg/m2 are given orally along with insulin injections.
Category
Treatment - Drugs

2

Description
For control group placebo capsules with dose of 100mg/m2 are given orally along with insulin injections.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Children Hospital
Full name of responsible person
Dr.Hosein Zaeri
Street address
City
Goragn

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Doctor Masoud Khoshnia
Street address
Falsafi educational department, Shast kola avenue
City
Gorgan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Golestan University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute

Full name of responsible person

Doctor Neda Mehrdad

Street address

Endocrinology and Metabolism Research Institute, Shariati Hospital, North Karegar Street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology and Metabolism Research Institute

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Doctor Hosein Zaeri

Position

Assistant Professor of Pediatrics and Pediatric Endocrinology and Metabolism

Other areas of specialty/work

Street address

Janbazan boulvard, Taleghani Children Hospital

City

Gorgan

Postal code

Phone

+98 17 3222 7720

Fax

Email

Dr.zaeri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Professor Maryam Razzaghy Azar

Position

Professor of Pediatrics and Pediatric Endocrinology and Metabolism

Other areas of specialty/work

Street address

No.23, Setareh Alley, North Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 6694 2903

Fax

Email

mrazar@tums.ac.ir, mrazar_md@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan university of Medical Sciences

Full name of responsible person

Doctor Hosein Zaeri

Position

Assistant Professor of Pediatrics and Pediatric Endocrinology and Metabolism

Other areas of specialty/work

Street address

Taleghani Children Hospital, Janbazan bulvard

City

Gorgan

Postal code

Phone

+98 21 3222 7720

Fax

Email

Dr.zaeri@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty