

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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 a double 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

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Name of organization / entity

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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 sizeTarget 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

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Falsafi educational department, Shast kola avenue

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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
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Endocrinology and Metabolism Research Institute,
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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
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
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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