

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of distillate of *Urtica Dioica* leaves on blood sugar of patients with type 1 diabetes mellitus

Protocol summary

Summary

The objective of this study is to determine the effect of distillate of *urtica dioica* leaves on blood glucose of patients with type 1 diabetes. A total of 30 patients with known type 1 diabetes, will be recruited in a clinical trial. Sample size consists of 30 patients. The patients are studied for 6 days. During the first three days, they don't receive any intervention and the baseline measures will be determined. They will take *urtica* distillate on the second three days. The carbohydrate counting of their foods will be equal on these two periods. The blood glucose will be monitored by continuous glucose monitoring system every 5 minutes on these 6 days. The patients are assigned to 10 groups of 3 patients each. The first group will receive 15 ml/M2 of the substance and next groups will receive 15 mL more than the previous group until the effect of substance or an adverse event appears. Total daily blood glucose and insulin will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008174585N1**

Registration date: **2011-02-03, 1389/11/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-03, 1389/11/14

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

Tehran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-03-23, 1390/01/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of distillate of *Urtica Dioica* leaves on blood sugar of patients with type 1 diabetes mellitus

Public title

The effect of distillate of *Urtica Dioica* leaves on blood sugar of patients with type 1 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of type 1 diabetes mellitus who are on the treatment with insulin, duration of diabetes equal or more than one year from the diagnosis, age more than 10 years, no chronic complication of diabetes, no systemic or concomitant disease Exclusion criteria: any stressful situation such as trauma, infectious disease, surgery, or acute illness

Age

From **10 years** old to **20 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medical faculty of Tehran
University of Medical Sciences

Street address

East Hemmat Exp. Way between Sheikh Fazlolah and
Shahid Chamran

City

Tehran

Postal code

1449614535

Approval date

2010-06-07, 1389/03/17

Ethics committee reference number

P/883

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

blood glucose

Timepoint

Every 5 minutes

Method of measurement

continuous glucose monitoring system

2

Description

total daily dose of insulin

Timepoint

daily

Method of measurement

record of total daily dose

Secondary outcomes

1

Description

blood pressure

Timepoint

daily

Method of measurement

blood pressure measurement device

2

Description

clinical manifestations and complaints

Timepoint

daily

Method of measurement

physical examination and medical history

Intervention groups

1

Description

The patients are assigned to 10 groups of 3 patients each. The first group will receive 15 ml/M2 of the substance and next groups will receive 15 mL more than the previous group until the effect of substance or an adverse event appears.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

H. Aliasghar Children's Hospital

Full name of responsible person

Prof. Maryam Razzaghy Azar

Street address

East Dastgerdi St. Modarres Exp. Way

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences (Pardis Hemmat)

Full name of responsible person

Dr Akbar Fotouhi

Street address

East Hemmat High Way

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences (Pardis Hemmat)

Proportion provided by this source

100

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**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Maryam Razzaghy-Azar

Position

Specialty in Pediatrics Subspecialty in Pediatric Endocrinology and Metabolism

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

Prof. Maryam Razzaghy-Azar

Position

Professor of Pediatrics and Pediatric Endocrinology and Metabolism

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Person responsible for updating data

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Email

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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