

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Study of Morus nigra L. on HbA1c in diabetic patient

Protocol summary

Summary

This is a one-stage and triple blind clinical trials with controls. All patients with type2 diabetes who referred to clinic of Imam Khomeini hospital in Khomeini city, after examination by a physician as having diabetes if they consent to participate in research are imported. Samples for this study consisted of 100 patients with type II diabetes who selected with convenience sampling method and with simple randomly selected using random numbers table placed in two groups of 50 people. In case group, 3 milliliters of alcoholic extract of leaves of Morus Nigra L. in a glass of water three times a day are given for 3 months. In the control group for 3 months placebo (Alcohol does mulberry leaf extract of Morus Nigra L.) are given. Baseline hemoglobin A1C test result during the three months and then evaluated by the laboratory to be analyzed together. In this study, two sample thief (Mrs.) Fix trained and justified in the study. The data collection instrument consisted is a questionnaire and hemoglobin A1C test. The questionnaire consisted of 21 questions that included demographic information and questions about physical activity patterns, daily physical activity, family history of diabetes and hemoglobin A1C test result was the first step. In the second stage and after 3 months of intervention hemoglobin A1C obtained and the result is recorded. The sample-thief in this research do not know the contents of the medicine. Also, patients are not aware of what medications; Statistician also deals with the raw data, so it is triple-blind study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407163227N5**

Registration date: **2016-08-13, 1395/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-13, 1395/05/23

Registrant information

Name

Ashraf Salehi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 5222 7550

Email address

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Recruitment status

Recruitment complete

Funding source

Arak Univercity of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Morus nigra L. on HbA1c in diabetic patient

Public title

effect of Morus nigra L. on diabetic

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria included: Patients over 18 years; Type II diabetes for at least a year; Patients with blood levels of glycosylated hemoglobin of 7 to 9%; Recourse to the diabetes clinic in Khomeini city; consent to participate in

research Exclusion criteria included: Pregnant women or those who are trying to conceive; lactating women; patients with physical and mental disorders; Patients who use herbal medicines, nearly as continuous doesn't; Patients who have a special diet; Patients who use drugs addressing specific; diabetics insulin consume; patients younger than 18 years; having severe stress in the past 8 weeks; allergic to herbal medicines; Patients who have a need to change the amount of medicine; Patients who need to change their weight; Patients who need to change the quality of life.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

no

Secondary trial Id

no

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Science

Street address

arak,sardasht,arak university of medical science

City

arak

Postal code

Approval date

2014-11-17, 1393/08/26

Ethics committee reference number

2-170-1393

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

HbA1C

Timepoint

Before intervention and 3 Months after intervention

Method of measurement

blood test and biosystem kit

Secondary outcomes

1

Description

fasting blood sugar

Timepoint

Before intervention and 3 months after intervention

Method of measurement

blood test and Glucose (GOD) Kit

Intervention groups

1

Description

In case group, 3 cc of alcoholic extract of leaves of Morus nigra L. in a glass of water three times a day are given for 3 months.

Category

Treatment - Other

2

Description

In the control group for 3 months placebo(Alcohol does mulberry leaf extract of Morus nigra L.) are given

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital of Khomeini City

Full name of responsible person

Hamid Momeni

Street address

Emam Khomeini Hospital, Modares square ,Khomein

City

khomain

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Arak University of Medical Science

Full name of responsible person

Dr. Mohammad Rafei

Street address

Arak University of Medical Science, Sardasht, Arak

City

Arak

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

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Science

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**

Arak University of Medical Science

Full name of responsible person

Hamid Momeni

Position

Faculty member of Arak University of Medical Science.

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Fax**Email****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*

