Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 Aug 2020

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 type 2 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: empty
Update count: 0

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

Registrant information
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Recruitment status
Recruitment complete
Funding source
Arak University 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; 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 Khomein City

Full name of responsible person
Hamid Momeni
Street address
Emam Khomeini Hospital, Modares square, Khomain
City
Khomain

Sponsors / Funding sources

1
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
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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
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

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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
empty