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

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

Registrant information
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Name of organization / entity
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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; 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**
- Empty

**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
City
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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 scientific inquiries

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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