Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the efficacy of gel and aqueous extract of Citrullus colocynthis (L.) Schrad in patients with type 2 diabetes compared to placebo gel

Protocol summary

Study aim

Evaluation of the efficacy of gel and aqueous extract of Citrullus colocynthis (L.) Schrad in patients with type 2 diabetes referring to Kerman diabetes clinic

Design

Randomized clinical trial, double blinded, control by placebo In this study, 84 patients with type 2 diabetes (in two groups of 42 people) who are willing to cooperate in the project and have criteria for entry into the study, constitute the target community. It is explained the study schedule to all participants. Patients refer to respectively according to inclusion criteria. Each patient consumes three metformin daily for two weeks and after receiving consent based on their inclusion in the study and the method of balanced block randomization with three blocks are divided into three groups.

Settings and conduct

1. Preparation of aqueous seed extract and pulp of Citrullus colocynthis (L.) Schrad 2. Gel formulation of aqueous seed extract and pulp Citrullus colocynthis (L.) Schrad 3. Preparation of placebo gel 4. Measurement and comparison of fasting blood glucose / 2 h glucose / insulin in three groups 5. Measurement and comparison of serum levels of creatinine, TG, cholesterol, HDL, SGOT, SGPT, ALP and Bilirubin in the three groups. 6. Determination and comparison of CBC, U/A, PT, PTT and HbA1C in the three groups The project is performed at Physiology and Neuroscience Research Center of Kerman University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Newly diagnosed patients with type 2 diabetes are based on the ADA 2011 criteria, including the age range of between 18-75 years, and there are no restrictions on the sex that they are treated with oral metformin. Exit criteria for diabetic patients include fasting blood glucose greater than 250 and hemoglobin A1C greater than 9%, insulin therapy, chronic inflammatory disease, chronic complications of diabetes, pregnancy, breast feeding, liver, renal and neurological diseases.

Intervention groups

Control group: (metformin and placebo gel) Intervention group: In one group, the appropriate amount of formulated gel in carboxymethyl cellulose (5%) is applied on the forearm with area 20 cm2 per day for 30 minutes. in the second group the aqueous extract is used in the traditional method.

Main outcome variables

FBS; 2 Hpp; Urea; Creatinine; SGOT; SGPT; ALP; Bilirubin; HbA1c; PT; PTT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090317001774N8**
Registration date: **2018-02-20, 1396/12/01**
Registration timing: **retrospective**

Last update: **2018-02-20, 1396/12/01**
Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

Mojgan Sanjari

Name of organization / entity

Kerman University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 34 1322 2506

Email address

msanjari@kmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-10, 1396/10/20
Expected recruitment end date
2018-02-09, 1396/11/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of gel and aqueous extract of Citrullus colocynthis (L.) Schrad in patients with type 2 diabetes compared to placebo gel

Public title
Evaluation of gel and aqueous extract of citrullus Colocynthis in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed type 2 diabetic patients according to ADA-2011 criteria Cases between the age group of 18-75 years Treated with oral medication (Metformin)
Exclusion criteria:
Diabetic patients with fasting blood glucose greater than 250 mg/dL and hemoglobin A1C level higher than 9% Treatment with insulin Chronic inflammatory disease Chronic complications of diabetes Pregnancy Breastfeeding Liver, kidney and neurologic diseases
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining patient's consent, the patients were classified into three groups according to inclusions criteria for study and balanced block randomization with triplex blocks. In one group, the appropriate amount of formulated gel in carboxymethyl cellulose (5%) is rubbed on the forearm with area 20 cm2 per day for 30 min. In the second group, the aqueous extract is used in a traditional method and the third group receives the placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinded-experiment, the groups are classified by the Research Center's expert that is not involved in the implementation of the project. This category preserved in the dark package envelope until the end of the design and final analysis at the research center. According to the traditional method group, there is no possibility of blindness for the physician and the patient, but the statistician is blind to the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2017-12-11, 1396/09/20
Ethics committee reference number
IRKMUREC.1396.1592

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Patient's blood glucose 2 hours after breakfast
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

2

Description
HbA1c measurement
Timepoint
0-90 days after start of the intervention
Method of measurement
Chromatography- %-=₹

3

Description
Measurement of serum urea in fasting state
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

4

Description
Measurement of serum creatinine level in fasting state
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

5

Description
Measurement of aspartate aminotransferase in serum
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

6

Description
Measurement of Alanine Transferase Level in Serum
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

7

Description
Measurement of alkaline phosphatase in serum
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

8

Description
Measurement of bilirubin in patient serum
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-Calorie meter

9

Description
Prothrombin time
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
Seconds - Serology

10

Description
Partial thromboplastin time
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
Seconds - Serology

11

Description
Blood glucose after 8 hours of fasting
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
mg/dl-spectrophotometer

Secondary outcomes

1

Description
Weight
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
Scale

2

Description
Blood pressure
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
Barometer

3

Description
Waist
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement
Meter

4

Description
Medicinal effects
Timepoint
0-30-60-90 days after start of the intervention
Method of measurement

Questionnaire

Intervention groups

1

Description
Intervention group: The appropriate amount of formulated gel in carboxymethyl cellulose (5%) is rubbed on the forearm with area 20 cm2 per day for 30 min.
Category
Treatment - Drugs

2

Description
Intervention group: Use of aqueous extract in a traditional method
Category
Treatment - Other

3

Description
Control group: Getting a Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Clinic
Full name of responsible person
Dr. Mojgan Sanjari
Street address
Somayeh Crossroads (Tahmasebabad)
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Kerman
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Kerman
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7616913555
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr.Abbas Pardakhti
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway
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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
Kerman University of Medical Sciences
Proportion provided by this source
90
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Mojgan Sanjari
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinology and Metabolism
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Person responsible for scientific inquiries

Contact
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Full name of responsible person

Dr. Mojgan Sanjari

Position
Associated professor

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology and Metabolism

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Navvabeh Salarizadeh

Position
PhD student

Latest degree
Master

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Biochemistry

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7617665976

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salarinavabeh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available