

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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- %= τ

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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 updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Navvabeh Salarizadeh

Position

PhD student

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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