Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of oxymel caper product on metabolic syndrom diagnostic indexes in patients with diabetes type 2

Protocol summary

Summary

Objective: The main aim of this study is to determine the effect of oxymel caper product on metabolic syndrom diagnostic criteria in patients with diabetes type II. Design: This study is a triple blind randomized clinical trial on patients with aged 65-30 years and with type 2 diabetes who despite reciewing full dose of oral medication according to ADA guideline, still do not control their diabetes and insulin injections refused and their metabolic syndrome has been approved based on diagnostic criteria of NCEP: ATPIII. Setting and conduct: The total number of patients is 42 persons who were randomly divided to three groups (two intervention and one control groups). In all groups including the control group, in addition to conventional therapies (anti-diabetic drugs), patients are received simple sugar syrup regarding to their diabetes and the first intervention group is received simple oxymel and the second control group is received caper oxymel as much as the first interventional group. Participants including major eligibility criteria: patients are included with aged 65-30 years and with type 2 diabetes who despite reciewing full dose of oral medication according to ADA guideline, still do not control their diabetes and insulin injections refused and their metabolic syndrome has been approved based on diagnostic criteria of NCEP: ATPIII patients are excluded with Dissatisfaction with continuing participation؛ Necessity of any new therapeutic intervension during the study based on endocrinologist؛ Breast feeding and lactation؛ Complications such as increasing blood presure, chest pain, fatigue during treatment؛ Renal problem with increasing creatinine and decreasing GFR less than 60؛ Any systematic disease which influence on trend of disease such as cardiac diseases, liver problems and malignancies؛Acute or sever complications of diabete such as DKA, hyperosmolar coma and sever hypoglycemia in recent 3 months؛ The critical illness which leads to hospitalisation in recent 3 months؛ Taking hyperglycemic agent such as immunosupressive and antileptic. Interventions: Intervention group1: Caper oxymel including 2000 mg hydroalcoholic extraction of capparis spinosa in oxymel 30 cc per day orally in 2-3 divided doses for 3 month. Intervention group2: Simple suger oxymel 30 cc per day orally in 2-3 divided doses for 3 month. Control group: Dextrose syroup (65%), 30 cc per day, orally in 2-3 divided doses for 3 month. main outcome measures (variables): During the study period (3 months), diagnostic criteria for metabolic syndrome including waist circumference, FBS, blood pressure and lipid profile as measurable outcomes of the study were determined at the beginning and end of the intervention. Moreover, in order to evaluate the effects or possible side effects of the treatment, other tests including SGPT, SGOT, ALP and creatinine were performed at Before, one month, two month and at the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100630175N1**
Registration date: **2017-01-15, 1395/10/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-15, 1395/10/26

Registrant information

Name

Hamideh Vahid

Name of organization / entity

Mashhad University of Medical Science- School of Traditiol Medicine

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research and Technology Vice-Chancellory of Mashhad University of Medical Science

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of oxymel caper product on metabolic syndrom diagnostic indexes in patients with diabetes type 2

Public title

The effect of caper oxymel on loosing weight, decressing blood suger and blood fat and lowering blood pressure in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients (type 2) whose disease has not been controlled inspit of taking complete oral medication based on ADA and they do not accept to take insulin؛ Ages between 30-65 years old؛ Definitive diagnosis of metabolic syndrom based on NECP:ATPIII diagnostic criteria exclusion criteria: Dissatisfaction with continuing participation؛ Necessity of any new therapeutic intervension during the study based on endocrinologist؛ Breast feeding and lactation؛ Complications such as increasing blood presure, chest pain, fatigue during treatment؛ Renal problem with increasing creatinine and decreasing GFR less than 60؛ Any systematic disease which influence on trend of disease such as cardiac diseases, liver problems and malignancies؛Acute or sever complications of diabete such as DKA, hyperosmolar coma and sever hypoglycemia in recent 3 months؛ The critical illness which leads to hospitalisation in recent 3 months؛ Taking hyperglycemic agent such as immunosupressive and antileptic

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences Administration, Building Qureshi, Daneshgah Ave.

City

Mashhad

Postal code

9138813944

Approval date

2016-10-08, 1395/07/17

Ethics committee reference number

IR.MUMS.REC.1395.361

Health conditions studied

1

Description of health condition studied

Diabete

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

waist circumference

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Using a tape in order to measure in cm

2

Description

Fasting blood suger

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Measuring by blood tests in mg/dl

3

Description

Lipid profil

Timepoint

Before and after intervention

Method of measurement

Measuring by blood tests in mg/dl

4

Description

HbA1c

Timepoint

Before and after intervention

Method of measurement

Measuring by blood tests in %

5

Description

Blood pressure

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Measuring by sphygmomanometer in mm/hg

6

Description

Microalbuminuria

Timepoint

Before and after intervention

Method of measurement

Measuring by urine tests in mg/l

7

Description

CRP

Timepoint

Before and after intervention

Method of measurement

Measuring by blood tests in mg/l

Secondary outcomes

1

Description

SGOT

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Measuring by blood tests in IU/L

2

Description

SGPT

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Measuring by blood tests in IU/L

3

Description

ALP

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Measuring by blood tests in IU/L

4

Description

Creatinie

Timepoint

Before in intervention, one month, two month and after intervention

Method of measurement

Measuring by blood tests in mg/dl

Intervention groups

1

Description

Intervention group1: Caper oxymel including 2000 mg hydroalcoholic extraction of capparis spinosa in oxymel 30 cc per day orally in 2-3 divided doses for 3 month

Category

Treatment - Drugs

2

Description

Intervention group2: Simple suger oxymel 30 cc per day orally in 2-3 divided doses for 3 month

Category

Treatment - Drugs

3

Description

Control group: Dextrose syroup (65%), 30 cc per day, orally in 2-3 divided doses for 3 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Science

Full name of responsible person
Hamideh Vahid

Street address
Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran sports hall, East Razi Ave.

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences, Building Qureshi, Daneshgah Ave

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

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
Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person
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Position
PhD student of Iranian Traditional Medicine and Complementary

Other areas of specialty/work

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Assistant Professor

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Other areas of specialty/work

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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