

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effects of carrot juice fortified with beta carotene on inflammatory factors, lipid profile and glycemic control in type 2 diabetes patient.

Protocol summary

Summary

The aim of this study is to evaluate the possible effects of daily intake of carrot juice fortified with 10 mg beta carotene on inflammatory factors, lipids, glycemic control in patients with type 2 diabetes (T2DM). To do this, 44 diabetic patients will be selected. Patients will be assigned randomly to one of the 2 intervention groups.

1. Plain carrot juice .2, carrot juice fortified with 10 mg beta carotene Each patient will consume 200 ml of carrot juice every day for 2 months with lunch and dinner. At the first and last visits, anthropometric, dietary and laboratory assessments will be performed for all patients. Primary outcomes are improvement in glycemic, inflammatory and lipid markers and secondary outcome is prevention of long-term diabetic complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812113465N1**

Registration date: **2011-12-19, 1390/09/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-19, 1390/09/28

Registrant information

Name

farideh tahbaz

Name of organization / entity

faculty nutrition and food science shahid beheshti university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sciences & Health Services

Expected recruitment start date

2009-12-23, 1388/10/02

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of carrot juice fortified with beta carotene on inflammatory factors, lipid profile and glycemic control in type 2 diabetes patient.

Public title

Carrot juice fortified with beta carotene and diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion: age between 40-65 years old, FBS Equal or geater than 126 mg/dl, non smoking patients, exclusin criteria: CRP > 10 mg/l , not taking multivitamins and minerals, not using insulin and fat lowering drugs

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 44

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

f_tahbaz@nnftri.ac.ir

Secondary trial Id

-

Registration date

2011-12-18, 1390/09/27

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci

Street address

West Arghavan St., Farahzadi Blvd., Shahrak Qods,

City

tehran

Postal code

1981619573

Approval date

2009-09-24, 1388/07/02

Ethics committee reference number

4356

2

Ethics committee

Name of ethics committee

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci

Street address

tehran- West Arghavan St., Farahzadi Blvd., Shahrak Qods,

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Postal code

1981619573

Approval date

2009-09-04, 1388/06/13

Ethics committee reference number

4356

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E 11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

assessment of serum beta carotene

Timepoint

At the beginning and after 2 months intervention.

Method of measurement

with HPLC

2

Description

assessment of serum inflammatory factors CRP, IL6

Timepoint

At the beginning and after 2 months intervention.

Method of measurement

with ELISA

3

Description

assessment of serum lipid profile TC,TG,LDL-C,HDL-C

Timepoint

At the beginning and after 2 months intervention.

Method of measurement

with autoanalyzer

4

Description

assessment of serum glycemic control such as fasting Glucose

Timepoint

At the beginning and after 2 months intervention.

Method of measurement

with autoanalyzer

5

Description

IR 9 LDL/HDL 9 TC/HDL

Timepoint

At the beginning and after 2 months intervention.

Method of measurement

calculate

Secondary outcomes

1

Description

improvement of serum antioxidant such as beta-carotene , complication in type 2 diabetic patient

Timepoint

Baseline and 2 month after intervention

Method of measurement

assessment of serum factors and improvement of health in patient

2

Description

improvement of inflammatory factors

Timepoint

Baseline and 2 month after intervention

Method of measurement

with instrument

3

Description

improvement of serum lipid profile

Timepoint

Baseline and 2 month after intervention

Method of measurement

with instrument

4

Description

improvement of glycemic profiles

Timepoint

Baseline and 2 month after intervention

Method of measurement

with instrument

Intervention groups

1

Description

intervention group 1: fortified carrot juice with10 mg beta-carotene

Category

Treatment - Other

2

Description

intervention group 2: 200 ml plain carrot juice per 200 mL group

Category

Treatment - Other

3

Description

group 1 :with their lunch (this was exchanged with one serving of bread). 8 weeks

Category

Treatment - Drugs

4

Description

group 2 : with their lunch (this was exchanged with one serving of bread). 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

National nutrition and food technology research institute

Full name of responsible person

Dr Farideh Tahbaz

Street address

West Arghavan St., Farahzadi Blvd., Shahrak Qods,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci

Full name of responsible person

Dr Majid hajifaraji

Street address

West Arghavan St., farahzadi Blvd., Shahrak Qods

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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

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci

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 Nutrition and food Technology , Shahid Beheshti University of Medical Sciences & Health

Full name of responsible person

Atena Ramezani

Position

M.S student in Nutrition and at present ph.D student in Nutrition in Tehran ,University of Medical

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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