Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 و LDL/HDL و 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,
City
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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
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West Arghavan St., farahzadi Blvd., Shahrak Qods
City
Tehran
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 peresent ph.D student in Nutrition in Tehran ,University of Medical

Other areas of specialty/work

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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