

Effect of a dietary fiber and magnesium supplement on endothelial dysfunction, inflammation and glycemic control markers in patients with type 2 diabetes mellitus. Randomized, double-blind clinical trial.

Submission date 01/05/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/06/2006	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2005-785-022

Study information

Scientific Title

Study objectives

Biomarkers of endothelial dysfunction (selectin 2, vascular cell adhesion molecules [vcam], and intercellular adhesion molecule [icam]) will be lower in the patients with dietary fiber and magnesium supplements than those without them.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The name of the ethical committee that gave approval for the trial is Ethics Subcommittee of the National Commission for Scientific Research, Institute of Mexican Social Security (Comisión Nacional de Investigación Científica, Subcomité de Ética, Instituto Mexicano del Seguro Social), 14/04/2005; reference number: 09-B5-61-2800/983 2005-785-022

Study design

Randomized, double-blind, clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes mellitus type 2

Interventions

There are four arms of treatment. All four groups received the best therapy available to control dm2 which include the ADA nutrition treatment guidelines. There was a nutritionist that gave specific suggestions according to each patient's needs, with an indication of losing weight if necessary. All patients received oral hypoglycaemic products and antihypertensive therapy as much as was needed to achieve the target levels of glucose and blood pressure. Patients were

randomised to receive one of the following interventions:

1. Active cookies and active tablets
2. Combination of placebo and active cookies
3. Combination of placebo and active tablets
4. Control group: placebo cookies and placebo tablets

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Biomarkers of endothelial dysfunction (selectin 2, vascular cell adhesion molecules [vcam]) and intercellular adhesion molecule [icam])

Secondary outcome measures

1. Serum levels of inflammation markers (interleukin-6, C-reactive protein)
2. Plasma levels of glycemic control markers (glycated hemoglobin and glucose)

Overall study start date

28/11/2005

Completion date

30/11/2006

Eligibility

Key inclusion criteria

1. Having diabetes mellitus type 2 (dm2) according to the American Diabetes Association (ADA) criteria
2. Male or female
3. Up to 48 months of dm2 diagnosis
4. Aged 30-70 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

400

Key exclusion criteria

1. Clinical evidence of chronic complications at the time of enrolment
2. Chronic diarrhea
3. Renal function impairment

Date of first enrolment

28/11/2005

Date of final enrolment

30/11/2006

Locations

Countries of recruitment

Mexico

Study participating centre

Ave Cuauhtemoc 330

Mexico Distrito Federal

Mexico

06720

Sponsor information

Organisation

Mexican Institute of Social Security (Instituto Mexicano del Seguro Social) (Mexico)

Sponsor details

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Sponsor type

Government

Website

<http://www.cis.gob.mx>

ROR

<https://ror.org/03xddgg98>

Funder(s)

Funder type

Government

Funder Name

Mexican Institute of Social Security (Instituto Mexicano del Seguro Social)

Funder Name

Fabrica de Galletas la Moderna

Funder Name

Laboratorio Silanes

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration