

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	☐ Prospectively registered
		☐ Protocol
Registration date 30/06/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 30/06/2006	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomized, double-blind, clinical trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Cuauhutemoc 330
Mexico Distrito Federal
Mexico
06720

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration