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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

Registration date
30/06/2006

Last Edited
30/06/2006

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Study design
Randomized, double-blind, clinical trial

Primary study design
Interventional

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