ISRCTN96579359 https://doi.org/10.1186/ISRCTN96579359

Effect of a dietary portfolio on metabolic syndrome

Submission date	Recruitment status	[_] Prospectively registered
08/12/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2012	Nutritional, Metabolic, Endocrine	

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
PICDS08-6

Study information

Scientific Title
A clinical trial of the effect of a dietary portfolio (nopal, chia seed, soy protein and oatmeal) on parameters associated with metabolic syndrome

Acronym
SNAC-MS

Study objectives
Patients with metabolic syndrome (MS) who use a portfolio-based dietary nopal, chia seed, soy protein and oats have a better response on the biochemical parameters of the SM and the area under the glucose curve and insulin in the test of glucose tolerance, compared with patients who do not consume this portfolio over a period of two months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committees of the Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran approved on the 19th March 2009 (ref: 1966)

Study design
Single centre randomised placebo-controlled double-blind parallel-arm study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
The patients with metabolic syndrome, once they have met with the selection criteria, will participate in two stages. The first one is to standardise the diet in all patients, so that the members are instructed to consume a diet low in saturated fat, according to ATPIII program and with a reduction in 500 calories to their usual diet for two weeks, the second stage consisted in the assignment treatment (placebo or dietary portfolio). By using a randomised by balanced block by an independent person to study, with duration of two months.

In this stage, the subjects consume the same diet that in the first stage less the calories contained in the dietary portfolio or placebo (250 calories). The subjects had a medical examination every month, and were also attended by the nutrition staff to evaluate the diet with a 24 hours-recall and every third days patients record the daily dietary intake.

The study consisted of four visits during the monitoring period. At the first visit take place a medical history, and glucose and insulin curve with 75g of glucose of 120 minutes. During each visiti 24 hour recall, application of questionnaire physical activity, anthropometry, serum parameters are measured.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nopal, chia seed, soy protein, oatmeal

Primary outcome(s)
1. Area under the curve (AUC) of the glucose, insulin and tryglicerides after of glucose tolerance test at baseline and at the end of the intervention
2. Serum leptin, adiponectin and C reactive protein at baseline and at the end of the intervention

Measures at baseline, two weeks, six weeks and ten weeks:
1. Anthropometric measurement
2. Physical activity
3. Resting blood pressure
4. Lipid profile: serum total cholesterol (TC), trygliceride (TG), HDL-cholesterol, LDL-cholesterol
5. Fasting serum glucose concentration
6. Fasting serum insulin concentration
7. Food intake

Key secondary outcome(s))
1. Polymorphism of ABCA1 R230C (rs9282541); Pro12Ala (rs1801282) and Gly972Arg (rs1801278) genes
2. G/I ratio, HOMA, QUICKI, Matsuda and Gutt indexes

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Mexican mestizos
2. Men and women aged 20 - 60 years
3. Body mass index (BMI in kg/m^2) between 25 and 39.9
4. Recruited from the surrounding community of Mexico City
5. Present three or more signs of metabolic syndrome following:
5.1. Fasting plasma glucose between 100 mg/dl and 126 mg/dl
5.2. Triacylglycerol (TG) level greater than 150 mg/dl
5.3. Low high density lipoprotein (HDL) cholesterol (less than 40 mg/dl for men, less than 50 mg /dl for women)
5.4. Waist circumference greater than 102 cm for men, greater than 88 cm for women
5.5. Systolic blood pressure greater than 130 mmHg and greater than 85 mmHg diastolic

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. Patients with glucose greater than or equal to 126 mmHg or diagnosed by a doctor with any type of diabetes, diseases that occur secondarily acquired obesity and diabetes
2. History of cardiovascular event
3. Weight loss greater than 3 kg in the last three months
4. Catabolic disease as cancer and acquired immune deficiency virus (AIDS)
5. Pregnancy
6. Smoking history
7. History of substance abuse or alcoholism
8. No subject should have taken any lipid-lowering medication, antihypertensive, hypoglycaemic, steroids, chemotherapy, immunosuppressant, radiation, and anorectics six month prior to treatment
9. Taking regular nutritional supplements
10. Systolic blood pressure greater than 160 mmHg or diastolic blood pressure greater than 100 mmHg

Date of first enrolment
01/08/2009

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Mexico

Study participating centre
Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran
Mexico
Mexico
14000

Sponsor information

Organisation
Institution of Science and Technology of Mexico City (Instituto de Ciencia y Tecnología del Distrito Federal) (Mexico)

ROR
https://ror.org/01fncf688

Funder(s)

Funder type
Government

Funder Name
Institution of Science and Technology of Mexico City (Instituto de Ciencia y Tecnología del Distrito Federal) (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes