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MADIAB study: To assess the effect of the Ma-Pi 2 MAcrobiotic DIet on the improvement of metabolic control in patients with type 2 diABetes and metabolic syndrome

Submission date
09/08/2013

Recruitment status
No longer recruiting

Registration date
27/09/2013

Overall study status
Completed

Last Edited
09/04/2015

Condition category
Nutritional, Metabolic, Endocrine

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
In this study, we are looking at the adults with type 2 diabetes and metabolic syndrome to assess the effect of the Ma-Pi 2 Macrobiotic Diet on metabolic control. Recent studies have shown that a diet high in whole cereals, vegetables and legumes while low in simple carbohydrates, refined cereals, fat and food of animal origin could be helpful in type 2 diabetes mellitus management. These results seemed to be confirmed by recent advances in the exploration and modeling of the gut microbiota. Our goal is to assess the effect of a diet with these characteristics: the Ma-Pi 2 macrobiotic diet. The study's findings should help to improve the well-being of diabetic patients with metabolic syndrome and to determine a new dietary approach to these diseases and related complications.

Who can participate?
This study aims to recruit 58 type 2 diabetic patients with metabolic syndrome of both genders, aged 45 to75 years.

What does the study involve?
Eligible patients will be enrolled in the study and randomly allocated to one of two groups to receive either the Ma-Pi 2 macrobiotic diet or a conventional standard diet. For 21 days they will be staying in two separate hotels in the same area in Italy, where they will receive all daily meals according to their group allocation. Blood tests and glucose level measurements will be carried out at the start of the study and after 21 days.

What are the possible benefits and risks of participating?
There may be immediate direct benefits to the subjects participating as described in previous studies such as reduction in their blood glucose levels and weight loss. The main risk could be dropping of glucose levels drastically and to avoid it they will be strictly monitored by the doctors and specialists involved.

Where is the study run from?
This study is run from the Endocrinology Area of the University of Campus Biomedico of Rome, Italy.

When is study starting and how long is it expected to run for?
The recruitment started in February 2013 and finished in April 2013. The second follow-up will finish in September 2013.

Who is funding the study?
The study is funded by UPM Un Punto Macrobiotico International Association, Italy.

Who is the main contact?
Professor Paolo Pozzilli p.pozzilli@unicampus.it
Dr Andreea Soare a.soare@unicampus.it

Contact information

Type(s)
Scientific

Contact name
Prof Paolo Pozzilli

Contact details
Endocrinology Area
University of Campus Bio-Medico
Rome
Italy
00128
+39 06 22541 9160
p.pozzilli@unicampus.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
Prot. 11/13

Study information

Scientific Title
A randomised controlled trial to assess the short-term effect of the macrobiotic diet Ma-Pi 2 in patients with type 2 diabetes and metabolic syndrome

Acronym

MADIAB

Study hypothesis
This study is designed to determine whether short-term administration of the macrobiotic Ma-Pi 2 diet improves metabolic control (improvement in glycemic profile, blood glucose levels, HbA1c, HOMA IR and plasma lipid fractions) in type 2 diabetic subjects with metabolic syndrome compared with the standard diet recommended for diabetic patients (according to the Italian Society of Diabetology and Italian Association of Diabetologists guidelines).

The null hypothesis is that there will be no reduction of studied metabolic parameters or that there will be no difference in metabolic improvement between the two dietary treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of University of Campus Biomedico, Rome, 26/02/2013, ref: Prot.n. 11/13 PAR ComEt CBM

Study design
Randomized controlled single-centre two parallel groups trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
Type 2 diabetes mellitus and metabolic syndrome

Interventions
The subjects enrolled in the study are randomized and consequently divided into two homogeneous groups to receive the two dietary treatments. Over a period of 21 days they are lodged in two separate hotels in the same area in Italy, where they receive all daily meals (respectively Ma-Pi 2 Macrobiotic meals and recommended standard diet for diabetic patients). Blood sample analyses, antropometrical and glucose profile measurements will be carried out at basal and after 21 days of the dietary interventions.
Since 27/04/2013 the protocol was integrated by a supplementary follow-up of 3 and 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary endpoint is to determine in the two study groups the percentage rate reduction of the following parameters: HbA1c, fasting blood glucose, 2 hours post-lunch blood glucose, HOMA IR, total cholesterol, cholesterol - low density lipoprotein (LDL), triglyceride, BMI, waist and hip circumference. We compare the reduction of these parameters obtained in the two study groups (Ma-Pi 2 diet vs recommended standard diet for diabetic patients according to the Italian Society of Diabetology and Italian Association of Diabetologists guidelines).

1. For HbA1c at time 0 (before dietary intervention on 05/04/2013) and after 21 days of the dietary interventions (on 27/04/2013), and then for the supplementary follow-up at 27/07/2013 and 27/10/2013.
2. For HOMA IR, total cholesterol, cholesterol - low density lipoprotein (LDL), triglyceride, BMI, waist and hip circunference at time 0 (before dietary intervention on 05/04/2013) and after 21 days of the dietary interventions (on 27/04/2013), and then for the supplementary follow-up at 27/07/2013 and 27/10/2013.
3. For fasting and 2 hours post-lunch blood glucose: daily from the 05/07/2013 to the 27/04 /2012, and then for the supplementary follow-up at 27/07/2013 and 27/10/2013.

Secondary outcome measures
1. Changes in renal function biochemical parameters (blood urea nitrogen, uric acid)
2. Changes in insulin-like growth factor (IGF1)
3. Changes in markers of inflammation (PCR, WBC, IL-6, TNF-alpha)
4. Changes in gut microbiota composition
5. Changes in body composition

Changes in renal function biochemical parameters (blood urea nitrogen, uric acid), changes in insulin-like growth factor (IGF1), changes in markers of inflammation (PCR, WBC, IL-6, TNF-alpha), changes in gut microbiota composition, changes in body composition: at time 0 (before dietary intervention on 05/04/2013) and after 21 days of the dietary interventions (on 27/04 /2013).

Overall study start date
27/02/2013

Overall study end date
27/09/2013

Eligibility

Participant inclusion criteria
1. Subjects affected by type 2 diabetes and metabolic syndrome
2. Subjects of both genders, aged 40 to 80 years
3. Subjects who able to sign the informed consent and to follow the study requests

4. Subjects with body mass index (BMI) >25 kg/m2 but <45 kg/m2
5. DM treated with diet only or oral hypoglycemic agents [sulfonylureas (SU), metformin (MF)] and / with GLP-1 (injecting or orally) alone and/or in combination but not insulin therapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
58

Participant exclusion criteria
1. Patients affected by type 1 diabetes mellitus or type 2 diabetes on insulin therapy
2. Patients with serious underlying medical conditions such as cancer, severe infections, severe psychiatric disorders
3. Patients who have done other clinical trials in the prior three months of this study
4. Known or suspected hypersensitivity to one or more ingredients of the diets
5. Patients undergoing cortico-therapy or other drugs that may interfere with the metabolism of carbohydrates
6. Patients undergoing antibiotic therapy

Recruitment start date
27/02/2013

Recruitment end date
01/04/2013

Locations

Countries of recruitment
Italy

Study participating centre
University of Campus Bio-Medico
Rome
Italy
00128

Sponsor information

Organisation
UPM Un Punto Macrobiotico International Association (Italy)

Sponsor details
Via San Nicola, 9
Tolentino
Italy
62029
+39 07 3396 1019
upm@unpuntomacrobiotico.it

Sponsor type
Charity

Funder(s)

Funder type
Charity

Funder Name
UPM Un Punto Macrobiotico International Association (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/08/2014		Yes	No
Other publications	post hoc analysis	26/03/2015		Yes	No