

# 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

<b>Submission date</b> 09/08/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/04/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### 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 to 75 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?

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### Type(s)

Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### **Study objectives**

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

### **Health condition(s) or problem(s) studied**

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 circumference 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

## Completion date

27/09/2013

## Eligibility

### Key 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/m<sup>2</sup> but <45 kg/m<sup>2</sup>
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

**Key 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

**Date of first enrolment**

27/02/2013

**Date of final enrolment**

01/04/2013

**Locations****Countries of recruitment**

Italy

**Study participating centre**

University of Campus Bio-Medico

Rome

Italy

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**Sponsor information**

## Organisation

UPM Un Punto Macrobiotico International Association (Italy)

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## 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?
<a href="#">Results article</a>	results	25/08/2014		Yes	No
<a href="#">Other publications</a>	post hoc analysis	26/03/2015		Yes	No