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Treatment of reactive hypoglycemia with macrobiotic Ma-Pi 2 diet as assessed by continuous glucose monitoring system

Submission date
02/02/2016

Recruitment status
No longer recruiting

Registration date
05/02/2016

Overall study status
Completed

Last Edited
29/04/2016

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

Background and study aims
Reactive hypoglycemia (RH) is a disorder where levels of glucose (sugar) in the blood become dangerously low following a meal (called hypoglycemic episodes). Nutritional therapy is recommended for people affected by RH. The macrobiotic Ma-Pi 2 diet is a nutritional therapy that improves glucose control in people with type 2 diabetes. The aim of this study is to investigate whether the Ma-Pi 2 diet improves blood glucose levels in patients affected by RH.

Who can participate?
Patients diagnosed with RH, aged 26 to 65.

What does the study involve?
Patients are randomly allocated to one of two groups. One group receives the control (low-glycemic index) diet for 3 days followed by the macrobiotic Ma-Pi 2 diet for a further 3 days. The other group receives the Ma-Pi 2 diet and then the control diet. All participants' blood glucose levels are measured throughout the study by using continuous glucose monitoring devices and glucometers.

What are the possible benefits and risks of participating?
There may be immediate direct benefits to the subjects participating - i.e. reduction of the number of hypoglycemic episodes. The main risk could be a drastic decrease in glucose levels and to avoid it participants will be strictly monitored by the doctors and specialists involved.

Where is the study run from?
The Endocrinology Area of the University of Campus Biomedico of Rome (Italy).

When is the study starting and how long is it expected to run for?
February 2014 to February 2015

Who is funding the study?
UPM Un Punto Macrobiotico International Association (Italy)

Who is the main contact?
1. Professor Paolo Pozzilli (p.pozzilli@unicampus.it)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
51/14

Study information

Scientific Title
A randomized crossover trial to assess the effect of the Ma-Pi 2 MAcrobiotic diet in the treatment of reactive HYPoglycemia with continuous glucose monitoring system (MAHYP)

Acronym
MAHYP

Study objectives
This study is designed to determine whether short-term administration of the macrobiotic Ma-Pi 2 diet improves metabolic control in non-diabetic subjects affected by reactive hypoglycemia (reduction of the number of hypoglycemic episodes and assessment of glycemic distributions through different readings by continuous glucose monitoring system) compared with a low-GI diet for reactive hypoglycemia – to date, there is no diet for treating this condition.

The null hypothesis is that there will be no reduction of the number of hypoglycemic episodes or that there will be no difference according to the dietary sequence administered.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the University Campus Bio-Medico of Rome, 30/09/2014, prot. 51/14

Study design
Interventional crossover single-centre trial

Primary study design
Interventional

Secondary study design
Randomised cross over 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
Reactive hypoglycemia

Interventions
The subjects enrolled in the study are randomized and consequently divided into two homogeneous groups to receive the two dietary treatments in opposite sequence. Over a period of 6 days they are lodged in a farm in Italy, where they receive all daily meals (Ma-Pi 2 Macrobiotic meals or a control low-GI diet for reactive hypoglycemia).
Anthropometrical measurements will be carried out at baseline and after 6 days of the dietary interventions. Glucose profile measurements will be performed throughout the trial by using continuous glucose monitoring and glucometers.

Intervention Type
Other

Primary outcome measure
Reduction of the number of episodes of reactive hypoglycemia (blood glucose level below 70 mg /dL) in patients affected by such condition during macrobiotic Ma-Pi 2 diet administration compared to a same period during the administration of a low-GI diet.

Secondary outcome measures
Glycemic distributions assessment through different readings (< 40; 41-50; 51-60; 61-70, 71-80, 81-90, 91-100, 101-110, 111-120, 121-130, 131-140, 141-150, 151-160, 161-170, 171-180 and > 180 mg/dL), measured and compared between the two dietary treatments

Overall study start date

01/10/2014

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Non-diabetic patients
2. Both sexes
3. Aged at least 18 years old
4. BMI between 18 and 35 kg/m2
5. Able to provide written informed consent and to follow the procedures of the protocol
6. Previous diagnosis of RH, though it was confirmed by MMT before the enrolment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Impaired fasting glucose/impaired glucose tolerance/diabetic patients
2. Subjects affected by insulinoma or by other hypoglycemic endocrine conditions
3. Patients affected by any neoplasia
4. Patients affected by any food behavior disorders
5. Pregnant women
6. Symptoms of hypocalcemia
7. Known or suspected hypersensitivity to any of the ingredients of the administered diets
8. Patients under vitamin K antagonists or corticosteroid treatment
9. Subjects under any drugs therapy which might interfere with glucose metabolism

Date of first enrolment
01/10/2014

Date of final enrolment
31/01/2015

Locations

Countries of recruitment

Italy

Study participating centre
Campus Bio-Medico University of Rome
Via Alvaro del Portillo 21
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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
We wish to publish our results as soon as possible

Intention to publish date
31/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request