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Safety of the Pronokal method in obese diabetic patients: The Diaprokal study.

Submission date
10/11/2014

Recruitment status
No longer recruiting

Registration date
28/11/2014

Overall study status
Completed

Last Edited
28/11/2014

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
Obesity (being extremely overweight) is the cause of a large number of chronic diseases. Many of them are related to lipid metabolism, such as dyslipidaemia (too much fats and cholesterol in the blood), metabolic syndrome (MS), or coronary and vascular diseases. Type 2 diabetes mellitus (T2DM) is one of the most common disorders in people who are obese. Obese T2DM patients also have the disadvantage that most of the medications used to treat T2DM may, in themselves, lead to weight gain. There are many different types of diets for the treatment and control of obesity. One diet that is highly recommended is a low-calorie diet, which works by limiting the intake of calories to between 800 and 1500 kcal per day. This type of diet reduces the intake of all essential nutrients into the body in a balanced way. It results in weight loss in the short term but does not prevent the patient from regaining weight in the long term. This is thought to be due to people not sticking to the diet or reducing the amount of energy they use (for example, by reducing the amount of exercise that they do). The protein diet (such as the PronoKal method), is a weight loss treatment based on a diet rich in high biological value proteins. It reduces the amount of fats and carbohydrates in the diet while, at the same time, providing the total amount of proteins necessary to maintain muscle mass. It thereby reduces the carbohydrates to a minimum, so that the body, after about 2 or 3 days, uses fat as a source of energy and creates ketone bodies to burn it. The diet is supplemented with essential vitamins and minerals. Studies on how successful the protein diet is show that it results in safe rapid weight loss which is maintained in the longer term. The protein diet may be particularly suitable for obese patients with T2DM. Some studies have shown that this type of diet not only results in weight loss, but it improves blood glucose and the glycated haemoglobin levels in patients with T2DM. Furthermore, it is also believed to have a therapeutic effect on the symptoms and control of this disease, which means that the patients may not need to take so much medication. Although several studies support the use of a protein diet in obese patients, including those with T2DM, there have been no in-depth studies looking at the effects on different clinical and pathophysiological indicators of the disease. Here, we want to compare the safety of the protein diet compared to the low-calorie diet and their effects on the metabolic control of T2DM and cardiovascular risk factors, sensitivity and insulin secretion.

Who can participate?
People aged between 30-65 with T2DM and a BMI of between 30-35.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are placed on a low calorie diet for 4 months. Those in group 2 are placed on a protein diet (Pronokal method) for 4 months. The two diets are then compared in terms of weight lost, safety, tolerability, effects on metabolic control of T2DM and effects on the risk of cardiovascular disease.

What are the possible benefits and risks of participating?
The protein diet may be particularly suitable for patients with type 2 diabetes mellitus and obesity. Some studies have shown that this type of diet not only reduces weight, but it improves blood glucose and the glycated haemoglobin levels in patients with T2DM. It is also believed to have a therapeutic effect on the symptoms and control of this disease, permitting medication to be reduced and lessening the risk factors. Subjects placed on the protein diet will undergo ketosis and must be under medical surveillance for the risk of liver and kidney alterations. The protein diet is recommended only for patients with normal liver and kidney function.

Where is the study run from?
Department of Endocrinology and Nutrition, Hospital del Mar (Spain)

When is the study starting and how long is it expected to run for?
October 2010 to June 2011

Who is funding the study?
Pronokal® Group (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PRO-PRO-2009-01

Study information

Scientific Title
Open, controlled clinical study to evaluate the safety of a protein diet (PronoKal method) vs a balanced, low-calorie diet for weight loss in obese diabetic patients.

Acronym
DIAPROKAL Study

Study objectives
This study aims to establish the equivalence in the safety of a protein diet compared to the low calorie diet, while at the same time, studying its effects on the metabolic control of DM and the cardiovascular risk factors, sensitivity and insulin secretion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comité Ético de Investigación Clínica del Instituto Municipal de Asistencia Sanitaria. 22/10 /2009
Barcelona, España.
2. Comitè Ètic d´ínvestigació Clínica de les Illes Balears, June 30, 2010. Palma de Mallorca, España.
3. Comité Ético de Investigación Clínica del Hospital Universitario Rio Ortega. Mars 27, 2010. Valladolid, España.
4. Comité Ético de Investigación Clínica del Hospital de Basurto. May 20, 2010. Basurto, Bilbao, España.
5. Comité Ético de Investigación Clínica de Galicia. April 20, 2010. Santiago de Compostela, España.
6. Subcomisión de Investigación Sanitaria del Hospital Universitario Virgen del Rocio de Sevilla. June 30, 2010. Sevilla, España.

Study design
Open, randomized (1:1), controlled, multi-centre, prospective, clinical trial with a 4-month follow-up to evaluate the safety of a protein diet (PronoKal method) vs a balanced, low-calorie diet.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obese type 2 diabetes mellitus patients

Interventions
The total study duration will be six months, i.e. 2-month recruitment (or selection period) and 4-month follow up.
The study will be divided into two periods:
1. A screening period to identify the subject, obtain the Informed Consent, and take a blood

analysis
2. A four month follow-up diet period, in which the subject is randomised into one of two study groups, and the safety and efficacy of the diet is evaluated

Intervention Type
Behavioural

Primary outcome(s)
To evaluate the safety and tolerability of a protein diet (PronoKal method) compared to a low-calorie diet (calorie intake 10% below basal metabolic rate, calculated using the FAO/WHO/UN formula21) in obese diabetic patients over a period of four months.

This will include measuring:
1. Weight and abdominal circumference
2. Capillary glycaemia and ketonemia
3. Blood pressure
4. Changes in the DM treatment
5. Adverse effects
6. Electrocardiogram
7. Changes in the DM treatment
8. Pancreatic β-cell reserve maintained

Key secondary outcome(s))
1. To evaluate the differences in weight loss between obese diabetic patients who follow a protein diet (PronoKal method) vs obese diabetic patients who follow a balanced, low-calorie diet
2. To evaluate the effectiveness of the protein diet vs the low-calorie diet on metabolic control in obese diabetic patients
3. To compare the determination of plasma mineral values (sodium, calcium, potassium, magnesium, chlorine) in both groups (patients with a protein diet vs patients with a low-calorie diet), at 4 months of following the diet for reducing weight
4. To evaluate the effect of dietary protein vs a low-calorie diet on cardiovascular risk (CV) between the baseline and final visits
5. To evaluate the effect of a protein diet vs low-calorie diet on the pharmacological requirements for the treatment of DM between baseline and final visits
6. To compare diet adherence in both groups (patients who follow a protein diet vs patients who follow a low-calorie diet)
7. To compare diet satisfaction in both groups (patients who follow a protein diet vs patients who follow a low-calorie diet)

Completion date
15/06/2011

Eligibility

Key inclusion criteria
1. Patients of both sexes aged between the ages of 30 and 65
2. Patients diagnosed with type 2 diabetes mellitus with less than 10 years of evolution, non-insulin-
dependent1, with pancreatic β-cell reserve maintained and GAD-negative
3. Patients with HbA1c ≤9

4. Patients with a BMI between 30 and 35
5. Informed consent (IC) form signed before study participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients over 65 years
2. Pregnant or breastfeeding patients
3. Patients with severe eating disorders, alcoholism or drug abuse
4. Patients with severe psychological disorders (e.g. schizophrenia, bipolar disorder)
5. Patients with hepatic impairment
6. Patients with renal impairment
7. Patients with type 1 diabetes mellitus or insulin-dependent, or currently in treatment with insulin, or candidates for insulin treatment within a short period of time
8. Patients with obesity caused by other endocrine diseases (except T2DM)
9. Patients with blood disorders
10. Cancer patients
11. Patients with cardiovascular or cerebrovascular diseases (heart rhythm abnormalities, recent myocardial infarction [<6 months], unstable angina, decompensated heart failure, recent cerebrovascular accident [<6 months])
12. Patients with gout
13. Patients with kidney stones
14. Patients with cholelithiasis
15. Patients with depression
16. Patients with electrolyte abnormalities
17. Patients with orthostatic hypotension
18. Patients with an altered or abnormal electrocardiogram

Date of first enrolment
15/10/2010

Date of final enrolment
15/06/2011

Locations

Countries of recruitment
Spain

Study participating centre
Departmento de Endocrinología y Nutrición, Hospital del Mar.
Barcelona
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Sponsor information

Organisation
Pronokal® Group

ROR
https://ror.org/03vjvtz41

Funder(s)

Funder type
Industry

Funder Name
Pronokal® Group (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration