Protein and lifestyle intervention to preserve muscle mass in obese older type 2 diabetes patients - a 13-week randomised, controlled exploratory study with a 24-week follow-up period.

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Primary: To investigate the effect on leg muscle mass in the test group compared to the control group in older obese type 2 diabetes patients after 13 weeks of interventionSecondary: - To investigate the effect on glycemic control in the test group...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON40400

Source
ToetsingOnline

Brief title
PROBE

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym
Diabetes Mellitus type II

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia
Source(s) of monetary or material Support: Publiek Private Samenwerking in het Topconsortia voor Kennis en Innovatie (TKI) Agri & Food , partners zijn Hogeschool van Amsterdam, TNO, Vialente Dietheek, Tromp Medical en Nutricia Research,Publiek Private Samenwerking in het Topconsortia voor Kennis en Innovatie (TKI) Agri & Food ;partners zijn Hogeschool van Amsterdam;TNO;Vialente Dietheek;Tromp Medical en Nutricia Research

Intervention

Keyword: Diabetes, Muscle, Obesity, Protein

Outcome measures

Primary outcome

Leg muscle mass (from dual-energy x-ray absorptiometry [DXA]) [kg]

Secondary outcome

Glycemic control:

- Oral-glucose-insulin sensitivity index (based on oral glucose tolerance test

[OGTT])

- HbA1c (mmol/mol)

- Fasting plasma glucose (mmol/l)

- 2h plasma glucose (mmol/l) (based on OGTT)

Body composition:

- Appendicular skeletal muscle mass (from DXA) [kg]

- Fat mass (from BodPod) [kg, %]

- Body Weight [kg]

Study description

Background summary

Diabetes type 2 is a chronic disease strongly related to aging and overweight. Older obese diabetes patients have a decreased metabolic stability including a disturbance of the glucose uptake and lipid metabolism. Besides, older people, and especially older obese people with diabetes are very vulnerable for loss of muscle mass. Muscle mass is important for physical functioning and mobility on one hand. On the other hand, it is an important organ for energy and substrate metabolism and therefore important for metabolic stability.
The incidence and burden of diabetes and obesity can be improved with a healthy lifestyle. Decreasing overweight is therefore an important focus in the standard diabetes care in order to handle or improve the diabetes. However, weight loss is usually related to loss of muscle mass, which could deteriorate metabolic stability and mobility on long term.
A recent study has shown that a newly developed nutritional supplement, high in protein, causes preservation of muscle mass, compared to an iso-caloric control product, in obese elderly on a hypo-caloric diet in combination with a training program during a 13 week randomized trial.
The current study was set up to investigate whether a nutritional supplement high in protein, compared to an iso-caloric control product, can have a positive effect on the preservation of muscle mass and on glycemic control in older overweight diabetes type 2 patients who are participating in a similar weight loss program, consisting of a hypo-caloric diet and a training program during 13 weeks.
The results of this clinical study may contribute to the development of a weight loss program for older obese type 2 diabetes patients.

Study objective

Primary: To investigate the effect on leg muscle mass in the test group compared to the control group in older obese type 2 diabetes patients after 13 weeks of intervention
Secondary:
- To investigate the effect on glycemic control in the test group compared to the control group in older overweight/obese type 2 diabetes patients after 13 weeks of intervention
- To investigate the effect on body composition in the test group compared to the control group in older obese type 2 diabetes patients after 13 weeks of intervention

Study design

Exploratory; randomized; controlled; double-blind; parallel-group;

single-centre study

Intervention

Test product: A high protein oral nutritional supplement (ONS)
Control product: An iso-caloric control drink with similar taste and appearance. Both products are in powder format and will be consumed after dissolving in water.
Both study products will be compared as part of a weight loss program consisting of a calorie restriction diet and a resistance type exercise protocol. In this study protocol will therefore be referred to the comparison of the test group (weight loss program including use of test product) versus the control group (weight loss program including use of control product).

Study burden and risks

Subjects should abide to a hypocaloric diet and 3 times a week exercise under supervision for 13 weeks. Besides, the following procedures will take place during study visits (screening and V1-V4): measuring blood pressure and pulse (2x), indirect calorimetry (2x), 3 day dietary- and activity diary (3x), measuring ECG and blood pressure in rest and during exercise (1x), venepuncture (2x), Oral Glucose Tolerance Test including 5 times blood sampling via cannula (2x), bring first-morning urine sample (3x), finger pricks (1x required during screening, 4x optional before and during OGTT), DXA scan (3x), anthropometrics (5x), measurement of muscle power (3x), measurement of physical performance (5x), BodPod (3x), BIA (3x), RAND and GI tolerance questionnaire (3x), RSE and HAD questionnaires (2x), product intake (daily 1 or 2 servings, for 13 weeks) and complete a product intake diary.
Subjects should arrive fasted at a study visit four times. In addition, subjects should refrain from any sort of intensive physical activity for 48 hours prior to the 2 visits on which OGTT is performed, should not consume any alcohol 24 hours prior to these visits, and should eat the same diner prior to these visits. During study participation, use of protein- or amino acid containing nutritional supplements is not permitted. In addition, subjects should not donate blood during study participation.
Based on the available data from previous studies no specific adverse effects are anticipated. However, complaints such as belching, feeling of fullness, nausea, dry mouth and thirst may occur.
Due to the presence of high protein and the predisposition of patients with type 2 Diabetes to renal diseases, patients are only eligible for study participation if the estimated Glomerular Filtration Rate at screening is >=60 mL/min. Moreover, parameters to assess renal function are monitored throughout the study.
Substituting the caloric value of proteins in the test product for carbohydrates in the control product may result into a higher post prandial glucose response after consumption of the control product. Therefore, the

carbohydrate composition of the control supplement is composed of a mix of fast and predominantly slow release carbohydrate sources to alleviate the post prandial glucose peak. In addition, both products are consumed in a caloric restricted regime and simultaneous with an exercise program, which would be expected to deliver benefits on blood glucose and lipid management. Furthermore, the potential occurrence of hypo- or hyperglycemic symptoms will be monitored throughout the study.
A light pain can be experienced during the placement of the cannula for blood sampling. Sometimes a blue spot appears afterwards at the place of the cannula. The amount of radiation that is experienced during the DXA scans (maximum 13,5 µSv per visit) is equal to one and a half to two times the average natural background radiation at sea level during one day. The DXA scan could possibly indicate signs of osteoporosis. When this is the case, subjects will be informed accordingly.
A healthy diet and exercise are very important for diabetes type 2 patients. During this study, subjects will receive intensive coaching in this. This could have a positive effect on the subject*s health. Because nutritional supplements are used in the study, no serious adverse events are expected. Subjects will be carefully screened for eligibility and during the study subjects will receive intensive coaching of dieticians (students) and adverse events and lab safety values will be reviewed by a physician.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age 55-85 years old, inclusive
2. Ambulant type 2 diabetes patients (verified by used medication for Diabetes). In the event no medication is used HbA1c should be > 53 mmol/mol (>7.0 %)
3. - BMI > 30 kg/m2 or
- BMI >27 kg/m2 in combination with a waist circumference > 88 cm for women and > 102 cm for men
4. Willingness that general practitioner will be notified on study participation
5. Written informed consent
6. Willingness and ability to comply with the protocol
7. Ability to comply with the exercise protocol as assessed by a sports physician.

Exclusion criteria

1. Specific medical history: any malignant disease during the last five years except for adequately treated prostate cancer without evidence of metastases, localized bladder cancer, cervical carcinoma in situ, breast cancer in situ and non-melanoma skin cancer, and other relevant medical history that could affect the study outcome as judged by the study physician.
2. Any gastrointestinal disease that interferes with bowel function and nutritional intake (e.g. constipation or diarrhoea secondary to neuropathy, diarrhoea due to chronic inflammatory bowel disease, gastroparesis, (partial) gastrectomy or any other procedure for stomach volume reduction, including gastric banding).
3. Wearing an electronic implant and /or pacemaker
4. Renal disease (estimated Glomerular Filtration Rate [eGFR] <60 mL/min as based on MDRD formula)
5. Hepatic disease (liver enzymes ALAT, ASAT, GGT or ALP greater than 3 times Upper Limit of Normal)
6. Use within 2 weeks prior to baseline and/or expected use during the study of:
- Corticosteroids for systemic use
- Antibiotics for systemic use
7. Use of insulin
8. Change in dose within three months prior to baseline of:
- Antidepressants
- Neuroleptics
- Lipid lowering medication

9. Specific dietary and/or lifestyle factors present within three months prior to baseline:
- Involuntary weight loss of at least 5%.
- Use of protein containing or amino acid containing nutritional supplements
10. Known allergy to cow*s milk and milk products or the ingredients of the study products
11. Known galactosaemia
12. Known lactose intolerance
13. More than 22 µg (880 IU) of daily Vitamin D intake from non-food sources (such as supplements and prescribed medication)
14. More than 500 mg of daily calcium intake from non-food sources (such as supplements and prescribed medication)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46790.056.14