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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21917

Source
NTR

Brief title
Probe

Health condition

Diabetes type 2, Obesity
(in Dutch: Diabetes type 2, obesitas)

Sponsors and support

Primary sponsor: Nutricia Research BV
Source(s) of monetary or material Support: The study is financed by a Public Private Collaboration within the Topconsortium for Knowledge and Innovation Agri & Food, an initiative of the Dutch Government. The study has been designed by Tromp Medical, Vialente Dietheek, The Netherlands Organisation for Applied Scientific Research – TNO, Amsterdam University of Applied Sciences and Danone Nutricia Research.

Intervention

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 DXA) [kg]
- Body weight [kg]

Study description

Background summary

This 13-week randomised, double blind, controlled study is designed to evaluate whether a high protein ONS, compared to an iso-caloric control product, would offer benefits on skeletal muscle mass preservation and glycemic control in older obese diabetes type 2 patients who participate in a weight loss program, consisting of a calorie restriction diet and predominantly resistance exercise.

The results of this clinical study may contribute to the development of a weight loss program for the obese older adult diabetes type 2 patient.

Study objective

H0: The effect of using test intervention is equal to the effect of the control intervention with respect to change in leg muscle mass in obese older adult patients with type 2 Diabetes after 13 weeks of intervention
H1: The effect of using test intervention is unequal to the effect of the control intervention with respect to change in leg muscle mass in obese older adult patients with type 2 Diabetes after 13 weeks of intervention

Study design

Time points primary and secondary parameters: V1 (week 0) and V3 (week 13)

Intervention

Duration of intervention: 13 weeks
Intervention group: A high protein oral nutritional supplement (ONS)

Control group: An iso-caloric control drink with similar taste and appearance

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).

Contacts

Public
Danone Nutricia Research
Danone Nutricia Research
Danone Research
Amsterdam
The Netherlands
+31 30 2095 000
Scientific
Danone Nutricia Research
Danone Nutricia Research
Danone Research
Amsterdam
The Netherlands
+31 30 2095 000

Eligibility criteria

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 ≥ 43mmol/mol (≥ 6.1%)

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. For patients who use SU-derivatives: a) Agreement of patient that his/her diabetes medication may be adapted b) Agreement of the treating physician to possible adjustment(s) of SU-derivative dose at the start and during the study, either by the study physician or by the treating physician based on advice of the study physician.
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: Instable Angina Pectoris, cardiac infarcts and/or cardiac surgery within 3 months prior to baseline, 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 investigator.
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 22µg (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)

15. Current alcohol or drug abuse in opinion of the investigator

16. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

17. Participation in any other study involving investigational or marketed products concomitantly or within four weeks prior to baseline

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-04-2014
Application type:	First submission

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
NTR-new	NL4357
NTR-old	NTR4497
Other	NA : Tif.2.C/A/0 / Nutricia Research

Study results

Summary results

Effect of an Enriched Protein Drink on Muscle Mass and Glycemic Control during Combined Lifestyle Intervention in Older Adults with Obesity and Type 2 Diabetes: A Double-Blind RCT. https://doi.org/10.3390/nu13010064