Bouncing Metformin Intervention (BMI) Study: a long term randomized controlled trial to invert early type 2 diabetes.

Published: 16-12-2021
Last updated: 06-05-2024

To study the potential of the daily use of a mini-trampoline or metformin added to the NHG - guided lifestyle to cure early type 2 diabetes in overweight and obese patients. PICO research question. What is the effect of the mini-trampoline or...

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

Summary

ID

NL-OMON51497

Source
ToetsingOnline

Brief title
BMI study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes mellitus, Type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Bethesda Diabetes Research Center
Source(s) of monetary or material Support: Bellicon AG,Provincie Drenthe;Stichting C.W.

de Boer;Bellicon AG

Intervention

Keyword: early type 2 diabetes, lifestyle, metformin, minitrampoline

Outcome measures

Primary outcome

Primary outcomes of the BMI study:

Remission of diabetes after 1, 2, 3 and / or 4 years.

Remission of diabetes is defined as an HbA1c level < 48 mmol/mol (6.5%) and an FPG <= 6.9 mmol/l in the absence of any diabetes medication (but metformin) or bariatric surgery.

Reduction of HbA1c.

Secondary outcome

Secondary outcomes of the BMI study are blood pressure, heart rate, need for additional pharmacotherapy, insulin resistance (with fasting insulin, C-peptide, FPG) , body weight, body mass index, waist-hip ratio, body composition, muscle strenght development of co-morbidity, development of infections, metabolic and biomarkers in blood and urine (predefined list, like Advanced Glycation Endproducts, AGE*s) , treatment satisfaction, quality of life (EQ5D-5L) and physical activity as well as cost utility & effectiveness analyses by a HTA expert (HTA = health technology assessment).

Study description

Background summary

Type 2 diabetes has a huge impact on morbidity, mortality and costs for the community worldwide. Early treatment may help to reverse type 2 diabetes. Smart approaches to improve lifestyle, body composition and insulin sensitivity may be successful, especially if started early. Therefore, we designed the Bouncing Metformin Intervention (BMI) Study.

Study objective

To study the potential of the daily use of a mini-trampoline or metformin added to the NHG -guided lifestyle to cure early type 2 diabetes in overweight and obese patients.
PICO research question. What is the effect of the mini-trampoline or metformin, added to routine care compared to routine care only, on the presence and development of early type 2 diabetes in overweight and obese patients?

Study design

This study is an open label RCT to study the effects of the daily use of a mini-trampoline (Bellicon R - also suitable for fragile persons) or metformin versus control group on predefined outcomes. After randomization (stratified for age and BMI), patients will be 1:1:1 allocated to group C (Controls), group B (Bouncing) or group M (Metformin), and subsequently be treated during an intervention period of 2 years, followed by an observation period of 2 years. All patients (N=300, n=100 per group) will receive lifestyle consultation according to the NHG standard - embedded in regular practice.

Intervention

Routine Care. All patients are treated according protocol and good clinical practice with counselling for a healthy lifestyle. All participants in all groups will note in an diary, once weekly, the duration, frequency, type and intensity of their physical activities/ exercises. Additionally, every year questionnaires will be used.

Intervention with the mini-trampoline. Participants in group B are trained to stimulate the adherence to the daily use of the mini-trampoline (15 minutes per day - possible more). This intervention will be specifically monitored by sensors.

Intervention with metformin for insulin sensitization. Participants in group M receive metformin, 850 mg up to 3 times daily, if tolerated, unless

contraindicated. The daily dose of metformin is minimized at 850 mg and maximized at 2550mg. In the BMI study, metformin is primarily used as a prevention drug.

Study burden and risks

The burden and risks of this study are minimal. In all study groups, we intend to improve the quality of life to reduce overweight / obesity and to invert early type 2 diabetes.
Mild burdens can be expressed as:
1. protocol visits (14)
2. venous punctures (8 x 40 ml in 4 years)
3. mild side effects of metformin use
4. muscle transient pain due to exercise

Contacts

Public
Bethesda Diabetes Research Center

Dr. G.H. Amshoffweg 1
Hoogeveen 7909 AA
NL
Scientific
Bethesda Diabetes Research Center

Dr. G.H. Amshoffweg 1
Hoogeveen 7909 AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Early type 2 diabetes diagnosed within 4 years before inclusion:
• FPG > 6.9 mmol/l and/or
• PPG > 11.0 mmol/l and/or
• HbA1c 48 - 64 mmol/mol
FPG = fasting plasma glucose; PPG = postprandial plasma glucose
Willing and able to use the Bellicon on a daily basis
BMI 25 - 40 kg/m2
Age 30 - 80 years

Exclusion criteria

HbA1c >64 mmol/mol
Use of antidiabetic agents during the last 2 months before inclusion
Compelling need for antidiabetic agent (e.g. SGLT2 inhibition)
Contra-indication or intolerance for metformin use
Bariatric surgery
Type 1 diabetes
Expected bad compliance
Serious psychiatric illness
Malignancy, except nonmelanoma skin cancer
Pregnancy or willing to become pregnant within 2 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2022
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Metformin HCL TEVA 850 mg
Generic name:	Metformin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-12-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-04-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2021-005568-23-NL
CCMO	NL79388.042.21