Diabeter: low dosis metformin in combination with yoghurt for the treatment of insulineresistance in persons with overweight

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Treatment of overweight persons with insulinresistance with a low dose metformin added to yoghurt. The early reduction of glucose, especially the postprandial glucose will hopefully slow the process from insuline resistance to diabetes mellitus....

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

Summary

ID

NL-OMON36139

Source
ToetsingOnline

Brief title
Influence of metformin with yoghurt on insulineresistance.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulinresistance, lipids

Research involving
Human

Sponsors and support

Primary sponsor: bouter

Source(s) of monetary or material Support: Lening Universiteit Wageningen

Intervention

Keyword: glucose, insulinresistance, low dose metformin, overweight

Outcome measures

Primary outcome

1 HbA1c

Secondary outcome

1 weight

2 bloodpressure

3 taste of the product

4 metformin serumlevels

5 Insulinresistence by Homa glucose /insulin ratio

6 lipids

7 compliance

Study description

Background summary

Biguaniden
Biguaniden are medicines, which make cells more sensitive to insulin, so they are used by patients with an insulinresistance like type 2 diabetes mellius in overweight patients.The biguaniden (e.g.. metfomin) also reduces the glucose production in the liver. The active substance in metformin is metformine .Metformin is since 1959 international available and works within1-3 hours.The total effect can be up to 5 to 6 hours. Symptomatic complaints as polydipsie disappear after a few days. It slows both the basal and post-prandial blood glucose levels. Up till now metformin is only taken by patients with diabetes mellitus to treat the metabolic syndrome, and it also has a positive influence on the lipid spectrum and blood pressure. We even see a slight weight loss. The effective dose of metfomin for a patient with diabetes mellitus is 2000mg a day

with a clear dose relationship efficacy: above the 2000mg metformin loses its efficacy and we see more side effects. A serious side effect of metformin is lactic acidosis which is related to the dose of metformine, alcohol use and renal impairment. In the past, studies have been done with patients with an increased risk of diabetes mellitus to treat them pre-emptive with metformin. This treatment resulted in two studies in a risk reduction of 30% of developing diabetes melitus.The idea of adding a low dose of metformine to nutrition for people with a high risk to develop a heart disease and or diabetes mellitus has never been done till now.

Study objective

Treatment of overweight persons with insulinresistance with a low dose metformin added to yoghurt. The early reduction of glucose, especially the postprandial glucose will hopefully slow the process from insuline resistance to diabetes mellitus. This reduce of the glucose only needs to be 1 mmol and we will see a reduce of 0,3-0,5% of the HbA1c, which can delay the devellopment of diabetes mellitus type 2

Study design

A yoghurt and metformin (variable dosis of 250mg and 450 mg) will be giving during 6 weeks to persons with overweight, body mass index more than 26, before administration of the first dosage, waist-side, bodyweight, bloodpressure are determined, bloodsamples are taken before consumption on day -14 ,day 0 start of the yoghurt consumption durung 6 weeks, day 42 bloodglucose ,HbA1c ,lipids and metformine levels are determined. A finger bloodglucose will be taken on day 21.

Intervention

Influence of metformin added to yoghurt on metabole control

Study burden and risks

During 6 weeks yoghurt with a low dose metformin will be taken bij healthy overweight persons ,3 times bloodsamples will be taken and once glucose in the finger will be taken ,a diary for taste of the yoghurt must be filled in daily

Contacts

Public
bouter

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

overweight BMI>26, Age>18 and <70, waist: man >92 cm and woman> 82 cm

Exclusion criteria

known with diabetes, hypertension or RR>150-90 mmHg,dyslipedemia inherrited or cholesterol >6.5 mmol/l, alcoholcomsumption above 20 units a week, serumcreatinine man >135umol/l and woman >110umol/l

Study design

Design

Study phase: 4

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2011
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Glucophage
Generic name:	metformin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	25-03-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-04-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
Other	Aangevraagd
EudraCT	EUCTR2010-019081-93-NL
CCMO	NL36086.044.11