Diabeter,influence of low dosis metformin added to yoghurt for the treatment of insulinresistence

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treatment of overweight persons with insulinresistance with a low dose metformine add to yoghurt The early reduce of glucose especially the postprandial will hopefully decrease this process. This reduce of the glucose only needs to be 1 mmol and we...

Ethical review	Not approved
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON36620

Source
ToetsingOnline

Brief title
metformine added to yoghurt influence on insulineresistence

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulinresistence, lipids

Research involving
Human

Sponsors and support

Primary sponsor: bouter
Source(s) of monetary or material Support: lening universiteit wageningen

Intervention

Keyword: glucose, insulinresistence, low dosis biguaniden, overweight

Outcome measures

Primary outcome

1 glucose and HbA1c

Secondary outcome

1 weight

2 bloodpressure

3 taste of the product

4 metformin serumlevels

5 Insulinresistence by Homa glucose /insulin ratio

6lipids

7compliance

Study description

Background summary

Biguaniden

Biguaniden are medicine which make cells more sensitive to insulin so they are used by patients with an insulinresistance like type diabetes meelius with overweight .The biguaniden (o.a. Metfomine) also reduces the glucose production in the liver.The active substance in metformine is metformine .Metformine 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 metformine are 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 metfomine for a patient with diabetes mellitus is 2000mg a day with a clear dose relationship efficacy
Above the 2000mg metformine looses its efficacy and we see more side effects.

A serious side effect of metformine is lactaatacidose witch is related to the dose of metformine, alcohol use and renal imparment. In the past, studies have been done with patients with an increased risk of diabetes mellitus to treat them pre-emptive with metformine. This treatment resulted in two studies to a risk reduction of 30% of developing diabetes melitus.The idea of adding a low dose of metformine to a 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 metformine add to yoghurt
The early reduce of glucose especially the postprandial will hopefully decrease this process. 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 containing metformin(variabel dosis ,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 vinger bloodglucose will be taken on day 21

Intervention

influence of metformine admitted to yoghurt on metabole control

Study burden and risks

during 6 weeks yoghurt with a low dose metformine 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 tast of the yoghurt must be filled in daily

Contacts

Public
bouter

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NL
Scientific
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 en woman> 82 cm

Exclusion criteria

known with diabetes ,hypertension or RR>150-90 mmHG,dyslipedemie 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:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	19-11-2010
Application type:	First submission
Review commission:	METC Medisch Spectrum Twente (Enschede)
Not approved Date:	14-02-2011
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	NL31713.044.10