Metformin, a weightreducing drug in the obese pediatric population?

Published: 15-10-2007
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The aim of this study is determine the efficacy and safety of Metformin as a weight reducing drug in the euglykemic, obese paediatric population.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30455

Source
ToetsingOnline

Brief title
Metformin, as a weightreducing drug.

Condition

- Other condition

Synonym
Obesity, overweight

Health condition

Obesitas (obesity)

Research involving
Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: Wetenschapsschapspot vakgroep

kindergeneeskunde MMC Veldhoven

Intervention

Keyword: metformin, Obesity, weightloss, weightreduction

Outcome measures

Primary outcome

Bodyweight

Secondary outcome

Effect on the cardiovascular risk profile

Effect on the quality of life

Study description

Background summary

The aim of this study is to determine the efficacy of metformin in tackling obesity, which is a growing problem in the pediatric population.

The study is designed as a randomised, placebo-controlled, double-blind trial, in which we will investigate the effect of metformin on the weight of obese, euglykemic children, as well as the effect on the cardiovascular risk profile and quality of life.

Therapy consists of metformin usage and a diet. The use of metformin is usually well tolerated. Possible side effects are most often of gastrointestinal origin.
Metformin is registered in the Netherlands for prescription in children with diabetes mellitus type 2 (ten years and older).

Study objective

The aim of this study is determine the efficacy and safety of Metformin as a weight reducing drug in the euglykemic, obese paediatric population.

Study design

The study is a randomised, placebo-controlled, double-blind trial.

Intervention

Metfromin (glucophage 500) and a diet.

Study burden and risks

Therapy consists of metformin usage and a diet. The use of metformin is usually well tolerated. Possible side effects are most often of gastrointestinal origin.
Metformin is registered in the Netherlands for prescription in children with diabetes mellitus type 2 (ten years and older).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Obesity
Age 10-18 years

Exclusion criteria

Diabetes mellitus

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:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Metformin hydrochloride
Generic name:	Metformin hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	15-10-2007
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	EUCTR2006-005765-19-NL
CCMO	NL15123.015.06