The effect of baclofen on food craving scores and binge eating episodes in obese subjects

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To establish the efficacy of 60 mg baclofen compared to placebo in inducing a decrease in food craving, as assessed by a food craving questionnaires (G-FCQ-T) over 6 months in obese subjects.

Ethical review	Not approved
Status	Will not start
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON37514

Source
ToetsingOnline

Brief title
The baclofen study

Condition

- Appetite and general nutritional disorders

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: via de SKWOSZ (stichting klinisch wetenschappelijk onderzoek slotervaartziekenhuis)

Intervention

Keyword: Baclofen, Binge eating, Foodcraving, Obese

Outcome measures

Primary outcome

Food-craving score, measured by the food craving questionnaire

Secondary outcome

Binge eating

Body weight

Study description

Background summary

At the moment, medicamental treatment options for obesity are limited. Pharmacotherapy can be chosen when there is less than 5% weight reduction after one year of lifestyle changing. However, the effectiveness of these medication, like orlistat and sibutramine, is moderate with an overall weight reduction of about 5-10% of the total body weight. Besides that, these drugs have significant side effects such as hypertension and insomnia for sibutramine and diarrhea and flatus for orlistat. Until 2010 subtramine was marketed and prescribed as an adjunct in the treatment of obesity along with diet and exercise. Since sibutramine has been associated with increased cardiovascular events and strokes the drug is withdrawn from the market.

The effects of baclofen on addiction is still under investigation. The gamma-aminobutyric acid B (GABA-B) agonist baclofen is registered for the treatment of spasms of skeletal muscles, muscle clonus, rigidity and pain caused by disorders such as multiple sclerosis or cerebral palsy. It is also injected intrathecal for the management of severe spasticity. Baclofen was approved by the FDA in November 1977.
Baclofen has already proven effective in substance abuse. In animal models of repeated drug abuse, baclofen reduces self-administration of a variety of drug reinforcers, including cocaine, d-amphetamine, metamphetamine, ethanol, nicotine, and heroin. Clinical trials of baclofen in the treatment of alcohol, cocaine and opiate use disorders have yielded encouraging results. In a randomized, double-blind placebo-controlled trial of baclofen in alcohol dependent patients, baclofen was effective in inducing abstinence from alcohol

as well as reducing alcohol intake, alcohol craving, and state anxiety. Baclofen may be equally efficacious in attenuating binge eating. It has been shown that baclofen reduced fat intake in rats under binge-type condition. In a human non-placebo controlled trial of 7 patients with binge eating disorder baclofen reduced the binge eating episodes with 50% in 5 patients.

Although results of these studies are promising, the effect of baclofen on food craving and weight reduction in obese subjects has insufficiently been studied in randomized trials.

Study objective

To establish the efficacy of 60 mg baclofen compared to placebo in inducing a decrease in food craving, as assessed by a food craving questionnaires (G-FCQ-T) over 6 months in obese subjects.

Study design

Clinical randomised controlled trial

Intervention

Baclofen will be started with an initial doses of 5 mg a day. Every day 5 mg baclofen extra will be added tot the dosage with a final maximum dosage of 20 mg three times a day.

Study burden and risks

The use of baclofen may cause sife effects. De side effects will be minimal and harmless. Patients will be contacted weekly by telephone to inform about the side effects of baclofen.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- BMI above 30
- Age 18 years or older
- obtained informed consent
- sufficient command of the dutch language

Exclusion criteria

- Diagnosis of type 1 or type 2 diabetes
- obesity induced by other endocrinologic disorders
- current or history of treatment with medication that may cause significant weight gain, within 3 months prior to screening

Study design

Design

Study phase:	3
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

Ethics review

Not approved

Date:	28-02-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL38499.048.11