Obelix Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28577

Source
NTR

Brief title
Obelix

Health condition

1. Morbid obesity in childhood (NLD: morbide obesitas bij kinderen);

2. obesity treatment in children.

Sponsors and support

Primary sponsor: Koepel Behandelcentrum Chronisch Zieken
Locatie Heideheuvel
Soestdijkerstraatweg 129
1213 VX Hilversum, The Netherlands
tel.: 0031 35 6881411
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email: info@KBCZ.nl
Principal Investigator: O.H. van der Baan-Slootweg, Pediatrician
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

BMI decrease after 26 weeks of treatment and after a follow up of 24 months.

Secondary outcome

1. (Decrease of) existing co-morbidities (liverfunction, cholesterol, lipids, oral GTT, bloodpressure, lungfunction, exhaled-NO, bio-impedance);

2. (Increase of) exercise tolerance;

3. (Increase of) fysical activity;

4. (Increase of) Quality of Life.

Study description

Background summary

The objective of this study is to compare a newly developed ambulatory programme with a maximal clinical intervention programme. Patients were randomly assigned to either clinical treatment, involving hospitalization for 26 weeks, or an intensive ambulatory programme. Both treatment programmes consist of an intensive family-based intervention including exercise, nutrition and behaviour modification for the children and their caregiver(s). In a pilot study we found that our clinical treatment programme could achieve a sustainable decrease in BMI for 1 year after fisnishing a six month treatment programme. Therefore a randomized controlled trial was set up to evaluate whether the efficacy of an inpatient treatment programme for morbidly obese children (8-18y) is superior to the best possible care in an ambulatory setting. To compare changes in BMI and BMI=z-scores, body composition, body circumferences, insulin sensitivity, bloodpressure, liverfunctiontest, lipid profiles and exercisetest.

Study objective

In morbid obesity in childhood (8-18y)inpatient treatment is superior to ambultory treatment regarding decrease in BMI-scores.

Study design

T0 Start of treatment programme;

T1 after 26 weeks of treatment;

T2 after a follow up of 12 months;

T3 after a follow up of 24 months.

Intervention

Inpatient treatment arm: multidisciplinary obesity treatment (diet, exercise and behaviour) for 26 weeks. Parents classes obligatory. Child is hospitalized monday through friday. Weekends at home with homework for the whole family.

Ambulatory treatment arm:
multidisciplinary obesity treatment (diet, exercise and behaviour) for 26 weeks. Parents classes obligatory. Child and parent(s) visit outpatient clinic 12 times in 26 weeks for a 4-6 hour programme per visit.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children, 8-18 y, with primary (exogenous, alimentary) obesity;

2. BMI equivalent to or greater then 35 in adults or over;

3. BMI equivalent to or greater then 30 in adults with serious obesity related comorbidity;

4. Conventional treatments have failed.

Exclusion criteria

1. Syndromal/chromosomal related obesity;

2. obesity because of endocrine diseases or obesity inducing medication;

3. boulimia;

4. psychiatric disorders;

5. IQ under 70;

6. no informed consent given.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2004
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	02-01-2008
Application type:	First submission

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
NTR-new	NL667
NTR-old	NTR1172
Other	: MEC 04/208.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Aerobic exercise in adolescents with obesity: preliminary evaluation of a modular training program and the modified shuttle test

Klijn PHC, Van der Baan-Slootweg, OH, Van Stel, HF, BMC Pediatrics 2007