CArdiometabolic Risk reDuctIOn by Rimonabant: the Effectiveness in Daily practice and its USE.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20796

Bron
NTR

Verkorte titel
CARDIO-REDUSE

Ondersteuning

Primaire sponsor: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameters/endpoints: Primary outcomes will be measured after 3, 6, and 12 months, and include waist circumference, plasma glucose, HbA1C and the use of rimonabant.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Despite therapeutic advances, cardio metabolic disease still remains an important cause of death worldwide. The endocannabinoid system seems to be a new target for multiple risk factor management as it modulates food intake and adipogenesis. Selectively blocking the cannabinoid CB1 receptor with rimonabant has been shown to improve waist circumference, HDL-cholesterol, triglycerides and insulin resistance.

Objective:
The primary objective is to assess the (cost)-effectiveness of reimbursing rimonabant plus lifestyle counselling (combination of dietary and exercise advise) on the use of rimonabant. Secondary, we will assess the safety and effectiveness of rimonabant when used in daily practice.

Study design:
Study arm A is a single blind randomized trial with randomization on general practice level. Study arm B is a double blind randomized placebo-controlled trial in which randomization is performed on patient level.

Nature and extent of the burden, risks and benefits associated with participation:

Participants selected for this study have multiple risk factors that could result in vascular disease. Participants in this study have the opportunity to reduce their risk and improve their health. The risk associated with this study concern taking venous blood for 4 times and experiencing transient side effects from the use of rimonabant (nausea +8% compared to placebo, diarrhoea +4% and dizziness +4%).

Doel van het onderzoek

In the RIO study programme, the efficacy of rimonabant was examined. The next step is to assess the use of rimonabant, its safety and effectiveness in daily practice. In daily practice people also have other diseases, may use other medication and may be less compliant to use rimonabant than in the studies performed in research centres. All these factors could influence the use and effect of rimonabant on cardiometabolic risk reduction and therefore need to be assessed.

Onderzoeksproduct en/of interventie

Participants in the different study groups receive no medication, rimonabant or placebo plus 3 life style counseling sessions

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

We aim to include people who fulfil at least the following inclusion criteria:

1. Informed consent must be obtained in writing for all subjects at enrollment into the study

2. Male or female 18 – 75 years of age

3. Willingness and ability to comply with the study protocol (including the lifestyle counseling)

4. Waist circumference >88 cm in women; >102 cm in men

5. Diabetes mellitus type 2 or an impaired fasting blood glucose > 6.1 mmol/l in venous plasma

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Participants are excluded from participation in the study if:

1. Pregnant or breast-feeding women, or women planning to become pregnant

2. Previous use of rimonabant

3. History of surgical procedures for weight loss (eg, stomach stapling, bypass)

4. Morbid obese patients (BMI > 40 kg/m2), history of bulimia or anorexia nervosa

5. Presence of any clinically significant endocrine disease

6. Severe renal dysfunction (creatinine clearance < 30 ml/min) or nephrotic syndrome

7. Known chronic hepatitis or clinically significant hepatic disease

8. Significant haematology abnormalities (haemoglobin < 100 g/L and/or neutrophils < 1.5 G/L and/or platelets < 100 G/L).

9. Cardiac status NYHA III or IV or ECG within 6 months showing acute changes

10. Any current malignancy or any cancer with the past five years (except adequately treated basal cell skin cancer or cervical carcinoma in situ)

11. History of seizure disorder

12. Acute psychiatric disorders or prolonged use within the last 3 months of neuroleptics.

13. History of severe depression that could be defined as depression which necessitated the patient to be hospitalized, or patients with 2 or more recurrent episodes of depression or a history of suicide attempt and/or prolonged use (> 1 week) within the last 3 months use of antidepressants (including bupropion).

14. History of alcohol or other substance abuse, use of hashish or marijuana use

15. Use of any investigational treatment (drug or device) within 30 days prior to screening

16. Prolonged use (> 1 week) within the last 3 months of systemic corticosteroids

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-09-2006
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-09-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL765
NTR-old	NTR776

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN63367873

Resultaten

Samenvatting resultaten

James PT, Rigby N, Leach R. The obesity epidemic, metabolic syndrome and future prevention strategies. Eur J Cardiovasc Prev Rehabil 2004;11:3-8.

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