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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20796

Source
NTR

Brief title
CARDIO-REDUSE

Sponsors and support

Primary sponsor: Maastricht University

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes will be measured during the visits and at follow-up including lipid profile, body weight, blood pressure, smoking, QALYs and costs.

Study description

Background summary

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%).

Study objective

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2006
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-09-2006
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	NL765
NTR-old	NTR776
Other	: N/A
ISRCTN	ISRCTN63367873

Study results

Summary results

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

Health council of the Netherlands. Obesity and Overweight. The Hague: Health council of the Netherlands, 2003:1-158.

Zimmet P, Alberti KGMM, Shaw J. Globac and societal implications of the diabetic epidemic. Nature 2001;414(6865):782-787.

Qureshi AI, Fareed M, Sure K, Kirmani JF, Divani AA. The relative impact of inadequate primary and secondary prevention on cardiovasculair mortality in the United States. Stroke 2004;35:2346-2350.

Depres J-P, Golay A, Sjostrom L. Effects of rimonabant on metabolic risk factors in overweight patients with dyslipidemia. New England Journal of Medicine 2005;353(20):2121-2133.

Van Gaal LF, Rissanen AM, Ziegler O, Rossner S. Effects of the cannabinoid-1 receptor blocker rimonabant on weight reduction and cardiovascular risk factors in overweight patients: 1-year experience from the RIO-Europe study. The Lancet 2005;365:1389-1397.

Kaper J, Wagena EJ, Willemsen MC, Van Schayck CP. Reimbursement for smoking cessation treatment may double the abstinence rate: Results of a randomised trial. Addiction 2005;100:1012-1020.

Banga JD, Man-Van Ginkel J, Sol-De Rijk BGM, Visseren FLJ, Westra TE. Handboek Vasculair risicomanagement door de nurse practitioner. Utrecht: UMC Utrecht, 2004.
