

CARDIOMETABOLIC Risk reDUCTIOn by Rimonabant: the Effectiveness in Daily practice and its USE

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/02/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym
CARDIO-REDUSE

Study objectives

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.

More information can be found below:

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. Global 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 cardiovascular 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medical Ethics Board Maastricht University Hospital/Maastricht University (AZM/UM) on the 30th August 2006 (ref: MEC 06-3-050).

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patient at cardiometabolic risk

Interventions

Participants in the different study groups receive no medication, rimonabant or placebo plus three life style counselling sessions.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rimonabant

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

01/04/2008

Eligibility

Key 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 enrolment into the study
2. Male or female 18 to 75 years of age
3. Willingness and ability to comply with the study protocol (including the lifestyle counselling)
4. Waist circumference more than 88 cm in women and more than 102 cm in men
5. Diabetes mellitus type two or an impaired fasting blood glucose more than 6.1 mmol/l in venous plasma

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key 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 (e.g., stomach stapling, bypass)
4. Morbid obese patients (Body Mass Index [BMI] more than 40 kg/m²), history of bulimia or anorexia nervosa
5. Presence of any clinically significant endocrine disease
6. Severe renal dysfunction (creatinine clearance more than 30 ml/min) or nephrotic syndrome
7. Known chronic hepatitis or clinically significant hepatic disease
8. Significant haematology abnormalities (haemoglobin less than 100 g/L and/or neutrophils less than 1.5 G/L and/or platelets less than 100 G/L)
9. Cardiac status New York Heart Association (NYHA) III or IV or Electrocardiogram (ECG) within six 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 three months of neuroleptics
13. History of severe depression that could be defined as depression which necessitated the patient to be hospitalised, or patients with two or more recurrent episodes of depression or a history of suicide attempt and/or prolonged use (more than one week) within the last three 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 (more than one week) within the last three months of systemic corticosteroids

Date of first enrolment

15/09/2006

Date of final enrolment

01/04/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Maastricht (UM)

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

University Maastricht (UM) (The Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Industry

Funder Name

This trial is initiated by the principal investigator C.P. van Schayck and in part financed by the Care and Public Health Research Institute and Sanofi-Aventis (The Netherlands).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No