ISRCTN63367873 https://doi.org/10.1186/ISRCTN63367873

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

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 14/02/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J Kaper

Contact details
University Maastricht (UM)
CAPHRI Research Institute
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2420

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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. 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.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/09/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
600

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/m^2), 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)

Sponsor details
c/o Prof. Dr. Van Schayck
Department General Practitioner Medicine
P.O.Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2314
onno.vanschayck@hag.unimaas.nl

Sponsor type
University/education

Website
http://www.unimaas.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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