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Rate Control Efficacy in permanent atrial fibrillation, a comparison between lenient versus strict rate control in patients with and without heart failure

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
13/02/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00392613

Secondary identifying numbers
NTR425

Study information

Scientific Title
Rate Control Efficacy in permanent atrial fibrillation, a comparison between lenient versus strict rate control in patients with and without heart failure

Acronym
RACE II

Study objectives
Lenient rate control is not inferior to strict rate control in patients with permanent atrial fibrillation with and without heart failure in terms of cardiovascular mortality and morbidity, neurohormonal activation, NYHA class for heart failure, left ventricular function, left atrial size, quality of life and costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
1. Lenient rate control: heart rate in rest <110 bpm
2. Strict rate control: heart rate in rest <80 bpm and during minor exercise <110 bpm

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Component of: cardiovascular mortality, heart failure, stroke, systemic emboli, bleeding, syncope, sustained ventricular tachycardia, appropriate shocks or anti-tachycardia pacing of ICD for ventricular arrhythmias, cardiac arrest, life-threatening adverse effects of rate control drugs, pacemaker implantation.

Secondary outcome measures
1. All cause mortality
2. All cause hospitalizations
3. Exercise tolerance (NYHA class)
4. Left ventricular function
5. Left atrial size
6. Quality of life
7. NT-proBNP
8. Hospitalization for heart failure
9. Syncope, sustained ventricular tachycardia, appropriate shocks or anti-tachycardia pacing of ICD for ventricular arrhythmias, cardiac arrest, and pacemaker implantations
10. Bleeding, any stroke, systemic emboli
11. Myocardial infarction confirmed by ECG and enzyme increase
12. Costs
13. Renal function

Overall study start date
01/01/2005

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Patients with persistent AF <12 months
2. Age <80 years
3. Resting heart rate >80 beats per minute
4. On oral anticoagulation

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Paroxysmal AF
2. Known contraindications for strict or lenient rate control
3. Unstable heart failure
4. Cardiac surgery
5. Any current stroke
6. Foreseen pacemaker or cardiac resynchronization therapy
7. Sick sinus syndrome or AV node conduction disturbances
8. Untreated hyperthyroidism
9. Inability to walk or bike

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
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Sponsor information

Organisation
University Medical Center Groningen (UMCG) (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Industry

Funder Name
Dutch Heart Foundation (Nederlandse Hartstichting [NHS]) (Netherlands) (ref: 2003B118)

Alternative Name(s)
Heart Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
Interuniversity Cardiology Institute (ICIN) (Netherlands)

Funder Name
Working group on Cardiovascular research (WCN) (Netherlands)

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Biotronik

Funder Name
Guidant

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Vitatron

Funder Name
Roche

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Sanofi Aventis (France)

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?
Protocol article	protocol	01/09/2006		Yes	No
Results article	results	23/08/2011		Yes	No