

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

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|-------------------|----------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 27/01/2006 | No longer recruiting | <input checked="" type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 27/01/2006 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 13/02/2019 | Circulatory System | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00392613

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (Netherlands)

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, AZ

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., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Sanofi Aventis (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Results article | results | 23/08/2011 | | Yes | No |
| Protocol article | protocol | 01/09/2006 | | Yes | No |