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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/01/2006		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
27/01/2006	Completed	[X] Results		
Last Edited 13/02/2019	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Groningen Netherlands 9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (Netherlands)

Sponsor details

Dr Isabelle C. van Gelder University Medical Center Groningen P.O. Box 30001 Groningen Netherlands 9700 RB +31 (0)50 3611327 i.c.van.gelder@thorax.umcg.nl

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, 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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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