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Targeted pharmacological reversal of electrical remodeling after cardioversion

Submission date 06/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/08/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 06/02/2015	**Condition category** Circulatory System	[_] 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
NCT00215774

Secondary identifying numbers
AFNET-B11

Study information

Scientific Title
Targeted pharmacological reversal of electrical remodeling after cardioversion

Acronym
Flec-SL

Study objectives
Targeted, short-term pharmacological reversal of electrical remodeling is not inferior to prevent recurrent AF after cardioversion when compared to standard long-term antiarrhythmic medication.

On 05/10/2009 the following changes were made to the trial record :
1. The target number of participants was changed from 760 to 575.
2. The overall trial end date was changed from 30/06/2008 to 01/05/2011.

On 13/10/2009 the target number of participants was changed from 575 to 635.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Ärztekammer Westfalen-Lippe and the Faculty of Medicine, Westfälischen Wilhelms University of Münster, November 2004, ref: 4 VII Kirchhof

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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

Interventions
Targeted, short-term pharmacological reversal of electrical remodeling is not inferior to prevent recurrent AF after cardioversion when compared to standard long-term antiarrhythmic medication.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to first recurrence of persistent AF

Secondary outcome measures
1. Time to first occurrence of a documented relapse of atrial fibrillation
2. Number of patients with persistent AF after 6 months
3. Number and total duration of documented AF episodes
4. Time to termination of trial medication
5. Number of hospitalizations due to atrial fibrillation
6. Number of visits without hospitalization
7. Number of serious adverse events of special interest
8. Evolution of left ventricular function
9. Quality of life

Overall study start date
01/03/2005

Completion date
01/05/2011

Eligibility

Key inclusion criteria
1. Documented persistent atrial fibrillation
2. Age of 18 years
3. Documented oral anticoagulation (international normalized ratio [INR] ≥2) for at least three weeks prior to inclusion, or exclusion of left atrial thrombi by trans-esophageal echocardiography
4. Written informed consent of the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
635

Key exclusion criteria
Exclusion criteria are based on the approval information of flecainide and include, among others, patients with known coronary artery disease or typical angina pectoris, patients with depressed left ventricular ejection fraction (<40%), patients with severely depressed renal or hepatic function, patients with overt thyroid disease, and patients with known Brugada syndrome, sinus node dysfunction or higher degree AV nodal block.

Date of first enrolment
01/03/2005

Date of final enrolment
31/10/2009

Locations

Countries of recruitment
England

Germany

United Kingdom

Study participating centre
University of Birmingham Centre for Cardiovascular Sciences
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
German Atrial Fibrillation competence NETwork (AFNET) (Kompetenznetz Vorhofflimmern) (Germany)

Sponsor details
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Sponsor type
Government

Website
http://www.kompetenznetz-vorhofflimmern.de/

ROR
https://ror.org/01spm3d88

Funder(s)

Funder type
Industry

Funder Name
German Atrial Fibrillation competence NETwork (AFNET) (Kompetenznetz Vorhofflimmern) with funds of the German Research Foundation (Deutsche Forschunggemeinschaft [DFG]) and the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF]) (Germany)

Funder Name
Meda Pharma (Germany)

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	01/11/2005		Yes	No
Other publications	publication with some data on the Flec-SL trial:	01/11/2007		Yes	No
Results article	results	21/07/2012		Yes	No
Results article	results	18/09/2012		Yes	No

Results article	results	09/10/2013	Yes	No