Early treatment of Atrial Fibrillation for Stroke Prevention Trial (EAST)

Published: 09-08-2011
Last updated: 29-04-2024

To test whether an early, comprehensive, rhythm control therapy can prevent adverse cardiovascular outcomes in patients with recent-onset atrial fibrillation (AF) compared to usual care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON41351

Source
ToetsingOnline

Brief title
EAST

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation. i.e. the heart's upper chambers (the atria) beating very rapidly and irregularly, resulting in an irregular pulse

Research involving
Human

Sponsors and support

Primary sponsor: Kompetenznetz Vorhofflimmern e.V., AFNET e.V., Germany
Source(s) of monetary or material Support: AFNET + EHRA

Intervention

Keyword: atrial fibrillation, cardiovascular complications, early treatment, rhythm control

Outcome measures

Primary outcome

A composite of cardiovascular death, stroke / transient ischemic attack (TIA), and hospitalization due to worsening of heart failure or due to acute coronary syndrome.

The 1st co-primary outcome parameter is defined as the time to the first occurrence of a composite of the above mentioned components. The 2nd co-primary outcome is nights spent in hospital per year.

Secondary outcome

Several secondary outcomes will be assessed in the study population. Key secondary outcomes: Each of the components of the primary outcome, time to recurrent AF, cardiovascular hospitalizations, all-cause hospitalizations, left ventricular function, quality of life, cognitive function, cost of therapy.

These and additional secondary outcome parameters will be assessed in the main trial and in investigator driven sub-studies.

Assessment of safety: The primary safety outcome comprises all deaths, the components of the primary efficacy parameter plus other adverse events related to the study intervention with special emphasis on proarrhythmia and complications due to interventions.

Study description

Background summary

Atrial fibrillation (AF) affects 1-2% of the population in Europe, doubles death rates, and causes deaths, severe strokes, heart failure, and acute coronary syndrome. Present management of AF, consisting of antithrombotic therapy, rate control, and often inconsistently applied rhythm control therapy, only partially prevents these complications. New, relatively safe antiarrhythmic agents and catheter-based isolation of the pulmonary veins provide potentially synergistic novel therapeutic options to maintain sinus rhythm, but their impact on major cardiovascular outcomes in AF remains controversial. Furthermore, long-lasting AF induces irreversible atrial damage and thereby renders sinus rhythm much more difficult to maintain.
EAST prospectively tests the hypothesis that an early, structured rhythm control therapy based on antiarrhythmic drugs and catheter ablation can prevent AF-related complications in patients with recent-onset AF when compared to usual care.

Study objective

To test whether an early, comprehensive, rhythm control therapy can prevent adverse cardiovascular outcomes in patients with recent-onset atrial fibrillation (AF) compared to usual care.

Study design

Investigator-driven, Prospective, parallel-group, randomized, open, blinded outcome assessment (PROBE) parallel-group interventional multi-centre trial. Phase IV.

Intervention

Patients will be randomized to early therapy or usual care. In the early therapy group, patients will receive either catheter ablation (usually by pulmonary vein isolation), or adequate antiarrhythmic drug therapy at an early time point. The initial therapy will be selected by the local investigator.
Upon AF recurrence, both modalities will be combined. Usual care will be conducted following the current ESC guidelines for AF treatment. In addition to antithrombotic therapy and therapy of underlying heart disease, usual care usually consists of an initial attempt to control symptoms by rate control therapy (bisoprolol, digoxin, digitoxin, metoprolol, verapamil).
Early rhythm control therapy will be guided by ECG monitoring.
All therapies applied in EAST are authority approved and mar-keted modalities.

Study burden and risks

Early, structured rhythm control therapy has the potential to improve prognosis

of AF patients by preventing AF-related cardiovascular complications.
As all treatments in EAST are in-line with clinical practice and recommended by guidelines, adverse events are expected to occur in similar clinical manifestations and at a comparable rate as the known adverse events of the approved therapies applied in the trial.
In light of the safety profile of the employed, established drugs and the frequency of AF and its possible cardiovascular complications the benefit-risk assessment turns out to be positive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Recent onset AF, i.e. AF with a known history of <= 1 year prior to randomisation
2. Risk for stroke as evidenced by

EITHER
a) one of the following: age > 75 years, prior stroke or transient ischemic attack (TIA)
OR
b) two of the following: hypertension, diabetes mellitus, left ventricular hypertrophy, age > 65 years, female sex, peripheral artery disease, kidney disease (MDRD stage III or IV), stable heart
failure (NYHA II or LVEF <50%), severe coronary artery disease (previous myocardial infarction, CABG or PCI)

Exclusion criteria

1. prior AF ablation or surgical therapy of AF
2. patients not suitable for rhythm control of AF
3. severe mitral valve stenosis
4. prosthetic mitral valve

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2011
Enrollment:	230
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-11-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-08-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-10-2015

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-021258-20-NL
ClinicalTrials.gov	NCT01288352;ISRCTN04708680
CCMO	NL37017.042.11