

Effects of hand-held paddle electrodes and biphasic shocks on the outcome of external cardioversion of atrial fibrillation

Submission date 15/06/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/11/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

MOBIPAPA

Study objectives

A randomised trial to assess the effects of biphasic shocks in combination with an anterior-posterior electrode position and the effect of hand-held shock electrodes on external electrical cardioversion outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled 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

With an assumed success rate of the monophasic shock wave form between 79% and 90%, we calculated a group size of 100 patients per group to achieve a statistical power of 0.8 (beta error 0.2) and a two-sided alpha level of 0.05 for each of the two hypotheses.

All shocks were delivered in an anterior-posterior electrode position. Patients were anaesthetised using standard procedures (either propofol or etomidate in combination with opioid analgetics). The trial was designed to detect an absolute difference in cardioversion success rate of 10% between two different shock wave forms (monophasic/biphasic) and

between two different electrode types (hand-held paddle electrodes/adhesive patch electrodes).

Due to training-dependent quality of the positioning of the cardioversion electrodes, a sequential design for the comparison of patch and paddle electrodes was chosen, while the simple exchange of the monophasic and biphasic defibrillators was tested in a randomised design.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Successful restoration of sinus rhythm by the cardioversion shock.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2004

Completion date

01/01/2005

Eligibility

Key inclusion criteria

All patients presenting with persistent atrial fibrillation and an indication for external cardioversion in the Department of Cardiology of the University Hospital Münster, Germany were consecutively screened for the trial.

Inclusion criteria:

1. A clinical indication for external cardioversion of atrial fibrillation
2. Documented atrial fibrillation prior to the procedure
3. To minimise thrombo-embolic complications, documented oral anticoagulation with phenprocoumon (international normalised ratio [INR] 2 - 3) for three weeks or exclusion of left atrial thrombi by trans-oesophageal echocardiography directly prior to the cardioversion procedure was required. Continuation of anticoagulation after cardioversion was recommended for all trial patients.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

Patients presenting with atrial flutter or atrial tachycardias

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2005

Locations**Countries of recruitment**

Germany

Study participating centre

Department of Cardiology and Angiology

Münster

Germany

48129

Sponsor information**Organisation**

University Hospital Münster (Germany)

Sponsor details

Albert-Schweitzer-Straße 33

Münster

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01856cw59>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University Hospital Münster (Germany) - Department of Cardiology

Funder Name

Medtronic Inc (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