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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/01/2005	**Overall study status** Completed	
Last Edited 05/11/2008	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Successful restoration of sinus rhythm by the cardioversion shock.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration