

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

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<b>Registration date</b> 31/01/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/11/2008	<b>Condition category</b> 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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D-48129

**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