Lung aeration and Lung perfusion Before and After Electrocardioversion

Published: 15-05-2012
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The objective of this study is to assess changes in lung aeration and lung perfusion in patients who will undergo electrocardioversion.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON37853

Source
ToetsingOnline

Brief title
Lung aeration and lung perfusion changes by Electrocardioversion

Condition

- Cardiac arrhythmias
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
atelectasis and lung perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: electrical impedance tomography, electrocardioversion, regional lung aeration, regionale lung perfusion

Outcome measures

Primary outcome

The main study endpoint is the change in regional lung aeration before and

after ECV, assessed by EIT.

Secondary outcome

Secondary study endpoint is the change in regional lung perfusion before and

after ECV, assessed by EIT.

Study description

Background summary

Short-term sedation is mandatory for electrocardioversion (ECV) for atrial fibrillation. Sedation, however, lowers the functional residual capacity and increases the risk of lung atelectasis due to hypoventilation, rendering patients prone to atelectasis-related pulmonary problems.
In atrial fibrillation, cardiac output is less than optimal and this could decrease lung perfusion. Stroke volume improves when sinus rythm is restored after ECV, which could lead to an improvement in lung perfusion.
Electrical Impedance tomography (EIT) is a real-time, non-invasive, bed-side, radiation-free continuous imaging technique able to detect changes of regional lung aeration and -perfusion.

Study objective

The objective of this study is to assess changes in lung aeration and lung perfusion in patients who will undergo electrocardioversion.

Study design

Observational study in patients under light sedation for electrocardioversion for atrial fibrillation.

Study burden and risks

In this observational study there are no risks involved for participating patients. Patient burden is minimal to none, and comprises of painless placement of an electrical impedance belt around the lower thorax and of the placement of a finger cuff to allow measurements of cardiac output by Nexfin.

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

Hemodynamically stable patients coming for electrocardioversion because of atrial fibrillation

Exclusion criteria

o Age < 18 years
o Presence of a pacemaker
o Presence of an automatic cardiac defibrillator
o Presence of any implantable pumps
o History of chronic obstructive pulmonary disease (COPD - defined as a forced expiratory volume in 1 second to a forced vital capacity ratio less than 0.65 and daily medication), restrictive pulmonary disease (evidence of chronic interstitial infiltration on chest radiograph), pulmonary thrombo-embolism, previous pneumectomy or lobectomy
o Known chronic or decompensated heart failure
o MET score <6

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL39752.018.12