A pilot study to investigate cardiac adverse effects of ropivacaine using local infiltration anaesthesia (LIA) technique during total hip arthroplasty (THA).

Published: 26-05-2013
Last updated: 24-04-2024

The primary objective of this pilot study is to describe *QRS widening, *QTc interval and other ECG findings (bradycardia, tachycardia, ST-segment elevation) pre-, peri- and postoperatively in a cohort of 20 patients, receiving in total 300 mg…

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

Summary

ID

NL-OMON38715

Source
ToetsingOnline

Brief title
CaRoH

Condition

- Cardiac arrhythmias

Synonym
Total Hip Artroplasty (THA) / total hip replacement

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Reinier de Graaf Groep

Intervention

Keyword: Cardiac adverse effects, Local Infiltration Anaesthesia (LIA), Ropivacaine, Total Hip Arthroplasty (THA)

Outcome measures

Primary outcome

The primary outcome is QRS widening (delta QRS) and delta QTc-intervals

measured with a 24 hour Holter ECG compared to baseline ECG.

Secondary outcome

Secondary study outcomes are bradycardia and/or tachycardia, and/or

ST-elevation compared to basaeline ECG.

Study description

Background summary

Ropivacaine as LIA is succesfully used for several years during THA in clinical practice. However, adverse effects of ropivacaine and in particular cardiac adverse effects for this route of administration are not clarified yet. The purpose of this study is to identify the occurence of cardiac adverse effects of ropivacaine administered by LIA during THA.

Study objective

The primary objective of this pilot study is to describe *QRS widening, *QTc interval and other ECG findings (bradycardia, tachycardia, ST-segment elevation) pre-, peri- and postoperatively in a cohort of 20 patients, receiving in total 300 mg ropivacaine as a local anaesthetic with LIA technique. All ECG data will be compared to baseline ECG, either as 12-lead ECG pre-operatively or as Holter ECG-data pre-operatively.
The secondary objective of this pilot study is to see if measurement of pre- and postoperatively 12-lead ECG together with 24 hour Holter ECG measurement starting before surgery is routinely feasible.

Study design

This prospective cohort pilot study examines the occurence of cardiac adverse effects of wound infiltrated ropivacaine in patients durin THA. The aim of this study is to include 20 evaluable patients. The occurence of cardiac adverse effects compared to the pre-operative ECG will be examined.

Study burden and risks

The pre- and post-operative ECG, and the 24 hour Holter ECG are the only burden for the patient. However this has no influence on the medical condition of the patient nor the mobilization of the patient.
This study has neither risks nor benfits for the patient. We anticipate that the results of this study will give more insight in cardiac adverse effects of ropivacaine after LIA and this might benefit future patients.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 7
Delft 2625 AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 7
Delft 2625 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients 18 years and older and scheduled for THA in Reinier de Graaf hospital.

Exclusion criteria

Allergy for ropivacaine.
Moderate or severe cardiac disease, bronchial asthma (severe valave insuffiency, angina pectoris 2/4 or more, congestive heart failure, rhythmic disorder).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	05-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL43674.098.13