Pharmacokinetic modelling of ropivacain in plastic surgery

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To determine the resorption of ropivacaïne and serum concentration we need 6 bloodsamples at t=0, t=30 min, t=1 hour, t=2 hour, t=4 hour, t=8 hour. A pharmacokinetic model will be made for each procedure using a software package MW/Pharm © (version...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON44042

Source
ToetsingOnline

Brief title
Pharmacokinetic modelling of ropivacain in plastic surgery

Condition

- Breast therapeutic procedures

Synonym
abdominoplastic, breast reduction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: pharmacokinetics, ropivacain, serum

Outcome measures

Primary outcome

The primary aim of this study is to describe the pharmacokinetic profile of

infiltrated ropivacaine. And to determine the serum concentration of

ropivacaine

Secondary outcome

Secundary outcomes:

1)Parameters that influence the absorption of local infiltrated ropivacaine

- Patientscharacteristics

- infiltrated area

- used dosage

2) Relatioship between postoperative pain and serum concentration

Study description

Background summary

In plastic surgery of the MMC, the emphasis is on the use of local anesthetics to minimize the post-operative pain. The effective control of postoperative pain is not only very desirable for humanitarian reasons, it is more often that this provides significant physiological benefits.
With reducing post operative pain, is postoperative recovery faster, minimizes clinical stay and return to work faster.
About the absorption of ropivacaine and serum concentration is limited evidence. That is why we want to study the serum concentration of local infiltrated ropivacaïne in venous blood.

Study objective

To determine the resorption of ropivacaïne and serum concentration we need 6 bloodsamples at t=0, t=30 min, t=1 hour, t=2 hour, t=4 hour, t=8 hour. A pharmacokinetic model will be made for each procedure using a software package MW/Pharm © (version 3.81).

Study design

A prospective observational pilot study.

Study burden and risks

regular care

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

> 18 years, breast reduction, abdominoplastic, local infiltration with ropivacain, endoscopic brow lift, minimal clinical stay of 1 day

Exclusion criteria

Intolerance of ropivacain, hepatic and/or renal failure, endoscopic brow lift patients who pay the operation themselves.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO

Date:	13-09-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21531
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54819.015.15
OMON	NL-OMON21531