Pharmacokinetic modelling of ropivacain in plastic surgery

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21531

Source
NTR

Health condition

serum
ropivacain
plasmaspiegel
ropivacaïne

Sponsors and support

Primary sponsor: Maxima Medical Centre
Source(s) of monetary or material Support: Maxima Medical Centre

Intervention

Outcome measures

Primary outcome

Parameters that influence the absorption of local infiltrated ropivacaine

- patientscharacteristics

- infiltrated area

- used dosage

Secondary outcome

Relatioship between postoperative pain and serum concentration

Study description

Background summary

Background:
In plastic surgery of the MMC, the emphasis is on the use of local anesthetics to minimize the postoperative 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, minimize clinical stay and return faster to work.
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.

Methods:
For this study will thirty healthy patients older than 18 years who are undergoing breastreduction, abdominoplastic and endoscopic browlift in Maxima Medisch Centrum. Exclusion criteria included contraindications for regional anesthesia, hypersensitivity for ropivacaine and any know heptic and/or renal failure.

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

Study objective

The serumconcentration of ropivacaïne 10mg/ml are low after local infiltration with the standard dosis.

Study design

t=0, t=30 min, t=1 hour, t=2 hour, t=4 hour, t=8 hour

Intervention

Take 6 bloodsamples after local infiltration with ropivacain.

Contacts

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Eligibility criteria

Inclusion criteria

healthy patients older than 18 years who are undergoing breastreduction, abdominoplastic and endoscopic browlift in Maxima Medisch Centrum

Exclusion criteria

contraindications for regional anesthesia, hypersensitivity for ropivacaine and any know heptic and/or renal failure.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial

Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-05-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44042
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5260
NTR-old	NTR5720
CCMO	NL54819.015.15
OMON	NL-OMON44042

Study results