Pre-incisional bupivacaine infiltration trocarincions, reduction of postoperative pain?

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The purpose of this study is to monitor whether preicncisional bupivacaine (bupivacaïne 0,5% with epinefrine 1:200.000), infiltration in trocarcincisions reduces postoperative wound pain.

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

Summary

ID

NL-OMON30342

Source
ToetsingOnline

Brief title
PITBUL 1

Condition

- Other condition
- Therapeutic and nontherapeutic effects (excl toxicity)
- Soft tissue therapeutic procedures

Synonym
incisional pain

Health condition

pijnbeleving

Research involving
Human

Sponsors and support

Primary sponsor: Ikazia Ziekenhuis
Source(s) of monetary or material Support: geen

Intervention

Keyword: bupivacaine infiltration, pre-incisional

Outcome measures

Primary outcome

reduction in postoperative wound pain (VAS score)

Secondary outcome

woundinfection

Study description

Background summary

Preincisional bupivacaine infiltration seems to be effective in postoperative painreduction in tonsillectomy, appendectomy, gynecologic and orthopedic procedures.

Study objective

The purpose of this study is to monitor whether preicncisional bupivacaine (bupivacaïne 0,5% with epinefrine 1:200.000), infiltration in trocarcincisions reduces postoperative wound pain.

Study design

Double blind randomisation in two groups: 1 (bupivacaïne group) and 2 placebo group).

Study burden and risks

questionnary (max half an hour)

Contacts

Public
Ikazia Ziekenhuis

Montessoriweg 1
3083 AN Rotterdam
Nederland
Scientific
Ikazia Ziekenhuis

Montessoriweg 1
3083 AN Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

all patients

Exclusion criteria

ASA III/IV
age under 18 yrs
bupivacaine allergy
peroperative conversion

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-08-2007
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL14477.101.06