Evaluation of most adequate pain medication in uterine artery embolisation for fibroma: PCA versus Epidural Analgesia.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29678

Source
Nationaal Trial Register

Brief title
PALE

Health condition

symptomatic uterine leiomyomata
embolization
post procedural pain
epidural analgesia
patient controlled analgesia

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis, Amsterdam (OLVG)
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

- painrelief (NRS)

Secondary outcome

- factors predicting amount of pain:

amount of embolization material used
reduction of volume of uterine leiomyoma

others:

- hospital stay

- costs

- adverse effects of analgesia

- patient overall satisfaction

- number of readmissions because of pain

Study description

Background summary

INTRODUCTION
During and after uterine artery embolization for uterin leiomyomata most patients experience severe pain, which was not controlled with current pain medication (PCM, diclofenac and dipidolor). Therefore this method was replaced by means of personal controlled analgesia. Unfortunately PCA was not sufficient to reduce pain to acceptable levels. Based on its promising results used in other procedures, we will compare the use of epidural analgesia with PCA.

Study objective

Epidural Analgesia shows promising results in other procedures and is therefore thought to be effective in embolization of uterine leiomyomata as well.

Study design

1. NRS: before, 1, 3, 6, 24 after treatment
2. questionnaire (phone call): 2 and 4 weeks after discharge.

3. overall satisfaction: 3 months after discharge

Intervention

Uterine artery embolization

group 1: PCA (morphin + ketamin)

group 2: epidural analgesia (bupivacain/naropin)

both groups: PCM, diclofenac, tramadol

Contacts

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Eligibility criteria

Inclusion criteria

1. Women

2. >18 years

3. Premenopausal

4. Symptomatic uterine leiomyoma confirmed by ultrasonography

5. Scheduled (and suitable) for uterine artery embolisation

Exclusion criteria

1. Wish for future pregnancy

2. Allergy to contrast material

3. Suspection of uterine malignancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-04-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable

Application type: Not applicable

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
NTR-new	NL1474
NTR-old	NTR1543
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A