

Effect van muziek op de klinische uitkomst na heupfractuur operaties (MCHOPIN): een multicenter gerandomiseerde studie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25655

Source

NTR

Brief title

MCHOPIN

Health condition

Proximal femur fracture

Delirium

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center

Rotterdam

Department of Surgery

P.O. Box 2040, 3000 CA Rotterdam, The Netherlands

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Delirium (DOS scale and clinical diagnosis by geriatrician)

Secondary outcome

- Pain (NRS)
- Anxiety (STAI-6)
- Medication use
- Postoperative complications
- Neurohormonal stress response (serum cortisol)
- Hospital length of stay
- 30-day mortality
- Nursing home length of stay
- 90-day readmission
- 90-day functional ability to perform daily living activities (Katz-ADL6)
- Cost analysis (direct medical costs)

Study description

Background summary

Proximal femur fractures are the most common fractures in the elderly. These elderly patients, often with significant comorbidity and polypharmacy, are at high risk for delirium, which increases the risk of other postoperative complications, a longer hospital stay and a reduced functional outcome. Recent systematic reviews and meta-analysis have shown a significant beneficial effect of perioperative music on postoperative pain and anxiety. Also, several studies have shown a reduced need for intraoperative sedative medication, as well as a reduction in postoperative analgesic medication requirement, when perioperative music as a non-pharmacological intervention was used. This study will investigate the effect of perioperative music on the clinical outcome in proximal femur fracture patients. The main objective of this study is to investigate whether music as an

intervention is effective in reducing the occurrence of postoperative delirium. Secondary objectives are the effects of perioperative music on pain, anxiety, medication use, postoperative complications, neurohormonal stress response, hospital length of stay, nursing home length of stay, 30-day mortality, 90-day readmission, 90-day functional ability to perform daily living activities and costs.

Study objective

Proximal femur fractures are the most common fractures in the elderly. These elderly patients, often with significant comorbidity and polypharmacy, are at high risk for delirium, which increases the risk of other postoperative complications, a longer hospital stay and a reduced functional outcome. Perioperative music has a significant beneficial effect on anxiety and postoperative pain, which are risk factors of delirium. The main objective of this study is to investigate whether music as an intervention is effective in reducing the occurrence of postoperative delirium.

Study design

90-days

Intervention

Perioperative recorded music

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with a proximal femur fracture undergoing surgical treatment
- Age ≥ 65 years old
- Provision of written informed consent by patient or proxy

Exclusion criteria

- Additional serious injuries or additional surgical procedures that may affect any of the outcome parameters
- Implant in situ in the affected hip
- Severe hearing impairment, defined as no verbal communication possible
- Patients unwilling or unable to comply with the intervention
- Preoperative planned hospital discharge and return to nursing home within 48 hours of admission
- Insufficient knowledge of the Dutch or English language to understand the study documents in the judgement of the attending physician or researcher
- Participation in another intervention study that might influence the duration of surgery or any of the outcome parameters

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control: Active

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-07-2018
Enrollment: 508
Type: Anticipated

Ethics review

Positive opinion
Date: 23-02-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52816
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6858
NTR-old	NTR7036
CCMO	NL64721.078.18
OMON	NL-OMON52816

Study results