

Effect of Music on the Clinical outcome after Hip fracture OPeratIoNs (MCHOPIN): a multicenter randomized controlled trial

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|------------------------------|---------------------------------------|
| Ethical review | Approved WMO |
| Status | Recruiting |
| Health condition type | Bone and joint therapeutic procedures |
| Study type | Interventional |

Summary

ID

NL-OMON52816

Source

ToetsingOnline

Brief title

MCHOPIN

Condition

- Bone and joint therapeutic procedures

Synonym

broken hip, proximal femur fracture

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Muziek als Medicijn Foundation

Intervention

Keyword: Delirium, Music, Pain, Proximal femur fracture

Outcome measures

Primary outcome

Delirium

Secondary outcome

Secondary outcomes are:

- Pain (Numeric Rating Scale (NRS; care as usual))
- Anxiety (State-Trait Anxiety Inventory 6 (STAI-6))
- Medication requirement
- Postoperative complications
- Hospital length of stay
- Nursing home length of stay
- 30-day mortality
- 90-day readmission
- 90-day Katz-ADL-6
- 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.

Study objective

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, 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 design

Multicenter randomized controlled trial.

Intervention

The intervention group will receive pre-operative, intraoperative and postoperative music as an intervention, the control group will not receive the music intervention. All patients will wear headphones before and during surgery. Patients in the intervention group can choose their preferred music.

Study burden and risks

Music has no known adverse effects. A lock on the music volume will be implemented to limit music volume. Part of the measurements and data collection is embedded in standard postoperative care, and part will be collected solely for study purposes, consisting of three questionnaires. All data will be collected during hospital stay and during one standard regular postoperative follow-up hospital visit. No additional hospital visits are necessary for this study. The study will be performed in proximal femur fracture surgery patients because of the high level of postoperative pain and high risk of delirium and other major postoperative complications in this study population, which influence length of hospital stay and costs. Incapacitated patients with dementia will be included, as this is a significant part of the target population with a substantially higher risk of delirium and postoperative complications. Overall, the burden and risks associated with this study are negligible.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

1. Patients with a proximal femur fracture undergoing surgical treatment
2. Age \geq 65 years old
3. Provision of written informed consent by patient or proxy

Exclusion criteria

1. Additional serious injuries or additional surgical procedures that may affect any of the outcome parameters
2. Simultaneous bilateral hip fracture
3. Implant in situ in the affected hip
4. Severe hearing impairment, defined as no verbal communication possible
5. Patients unwilling or unable to comply with the intervention

6. Preoperative planned hospital discharge and return to nursing home within 48 hours of admission
7. Insufficient knowledge of the Dutch or English language to understand the study documents in the judgement of the attending physician or researcher
8. 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 |
| Primary purpose: | Prevention |

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 05-03-2019 |
| Enrollment: | 452 |
| Type: | Actual |

Ethics review

| | |
|--------------------|---------------------------------------------------------------------|
| Approved WMO | |
| Date: | 08-10-2018 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO | |
| Date: | 04-10-2021 |
| Application type: | Amendment |

| | |
|--------------------|---------------------------------------------------------------------|
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO | |
| Date: | 23-11-2022 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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

ID: 25655
Source: NTR
Title:

In other registers

| Register | ID |
|----------|------------------------------------|
| Other | Nederlands Trial Register: NTR7036 |
| CCMO | NL64721.078.18 |
| OMON | NL-OMON25655 |