Reducing pain and discomfort during and after bone marrow aspiration

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22677

Source
Nationaal Trial Register

Brief title
REPADI

Health condition

Bone marrow aspiration and biopsy
Pain
Anxiety

Sponsors and support

Primary sponsor: MC Slotervaart
Source(s) of monetary or material Support: Stichting klinisch wetenschappelijk onderzoek Slotervaartziekenhuis

Intervention

Outcome measures

Primary outcome

-Visual Analogue Scale (VAS) for pain, directly after the procedure

- Visual Analogue Scale (VAS) for anxiety, fear for a next bone marrow aspiration and biopsy measured two weeks after the procedure

Secondary outcome

- Fear of Pain Questionnaire-III

- VAS for pain and anxiety at other moments than described at the main study parameters

- VAS for discomfort

- Possibility to follow instructions during the procedure

Study description

Background summary

A bone marrow aspiration and biopsy (BMAB) is a diagnostic medical intervention which is generally conducted with only local anaesthesia. Most of the patients experience discomfort and pain during this procedure and do not favour a next BMAB. No strict guideline exists on the use of pain and anxiety medication before a BMAB. In our hospital setting two different premedication schemes are used for pain and anxiety reduction. This study will investigate the different schemes of premedication on the pain during and after a BMAB and for the fear for a possible next BMAB. The main objective is to investigate which premedication scheme reduces best the pain during and after a BMAB and which premedication scheme reduces best the fear for a possible next BMAB. We will conduct a double-blind randomized controlled study and adult patients with an indication to undergo a first bone marrow aspiration and/or biopsy will be included. The two different premedication schemes consist of 1: lorazepam 1mg and paracetamol 1000mg both oral administration and 2: midazolam 7,5mg and morphine 10mg both oral administration. The primary study endpoints are the Visual Analogue Scale (VAS) for pain, scored directly after the procedure and fear for a next BMAB scored on a VAS for anxiety two weeks after the procedure. Secondary endpoints are

discomfort and patient related factors for pain experience.

Study objective

The main objective of this study is to investigate which premedication scheme reduces best the pain during and after a bone marrow aspiration and biopsy and reduces best the fear for a possible next bone marrow aspiration and biopsy.

Study design

VAS for pain directly after procedure, VAS for anxiety, fear for a next bone marrow biopsy, 2 weeks after the procedure

Intervention

Group 1: midazolam 7,5mg, oral, single dose AND morphine 10mg, oral single dose

Group 2: lorazepam 1mg, oral single dose AND paracetamol 1000mg, oral, single dose

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with an indication to undergo a first bone marrow aspiration in MC Slotervaart

2. Age > 18 years

3. Patient is capable to give informed consent

Exclusion criteria

1. Known allergy for any of the study medicines

2. Pregnancy

3. In hospital patients

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2016
Enrollment:	48
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-10-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42943
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5957
NTR-old	NTR6138
CCMO	NL58525.048.16
OMON	NL-OMON42943

Study results