Reducing pain and discomfort during and after bone marrow aspiration

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42943

Source
ToetsingOnline

Brief title
REPADI

Condition

- Other condition
- Haematological and lymphoid tissue therapeutic procedures

Synonym
Bone marrow aspiration and biopsy, bone marrow biopsy

Health condition

Pijn en angstbeleving

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Stichting klinisch wetenschappelijke onderzoek Slotervaartziekenhuis.

Intervention

Keyword: Anxiety, Bone marrow examination, Pain management

Outcome measures

Primary outcome

Main study parameters

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

- Visual Analogue Scale (VAS) for anxiety, fear for a next BMAB two weeks after

procedure

Secondary outcome

Secondary study parameters/endpoints

- Fear of Pain Questionnaire-III

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

parameters

- 5 point Likert scale, fear for a BMAB

- VAS for discomfort

- Possibility to follow instructions during the procedure

Study description

Background summary

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 pre-medication schemes are used for pain and anxiety reduction. This study will investigate the different schemes of pre-medication on the pain during and after a BMAB and for the fear for a possible next BMAB.

Study objective

The main objective of this study is to investigate which premedication scheme reduces best the pain during and after a BMAB and reduces best the fear for a possible next BMAB. Other objectives are the influence of the different medication schemes on discomfort and if there are other patient related factors that have influence on pain and anxiety.

Study design

Study type and design: This study will be a double blind randomized intervention study comparing two different premedication schemes for BMAB. We will compare lorazepam 1mg and paracetamol 1000mg orally one hour before the procedure with midazolam 7,5mg and morphine 10mg orally one hour before the procedure.

Intervention

Intervention treatment:
Midazolam 7,5mg, oral, single dose + morphine 10mg, oral, single dose
- Midazolam is a benzodiazepine with anxiolytic, sedative and possible muscle relaxant and anti-convulsive characteristics. Anterograde amnesia is also described by the use of midazolam. Midazolam is used before and during therapeutic and diagnostic procedures because of its sedative component. When using midazolam the concentration and reaction is affected, therefore driving a car is not recommended.
- Morphine is an opium alkaloid with a strong analgesic effect. Morphine is used for severe acute and chronic pain. Morphine is commonly used as premedication before anaesthesia and as analgesic during anaesthesia. Concentration and reaction is affected if using morphine, therefore driving a car is not recommended.

Control treatment:
Lorazepam 1mg, oral, single dose + paracetamol 1000mg, oral, single dose
- Lorazapam is a benzodiazepine with as main characteristic the anxiolytic effect. Anterograde amnesia is also described by the use of lorazepam. Lorazepam is indicated for short term treatment of anxiety and stress. Lorazepam is also used as pre-treatment before operative procedures. Concentration and reaction is affected after using lorazepam, therefore driving

a car is not recommended.
- Paracetamol is and acetanilide derivate with analgesic and antipyretic effect. It is commonly used for mild to moderate pain. It a very well tolerated drug.

Study burden and risks

Patients undergo a BMAB as normal, except for the premedication scheme which will be given in a randomized order. Both premedication schemes under investigation are used for many years in our hospital and have acceptable side effects. Patients need to fill in a questionnaire on anxiety and a number of scores on pain, discomfort and fear at four moments in time: before the procedure, directly after the procedure, 2 hours after the procedure and 2 weeks after the procedure. No extra visits are needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

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 written 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
Primary purpose:	Treatment

Recruitment

NL

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

Medical products/devices used

Product type:	Medicine
Brand name:	lorazepam

Generic name:	lorazepam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	midazolam
Generic name:	midazolam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	morphine
Generic name:	morphine sulphate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	paracetamol
Generic name:	paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-10-2016
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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: 22677
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-002906-38-NL
CCMO	NL58525.048.16
OMON	NL-OMON22677

Study results

Date completed:	28-11-2018
Actual enrolment:	42