Reducing pain and discomfort during and after bone marrow aspiration

Gepubliceerd: 19-10-2016 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22677

Bron
Nationaal Trial Register

Verkorte titel
REPADI

Aandoening

Bone marrow aspiration and biopsy
Pain
Anxiety

Ondersteuning

Primaire sponsor: MC Slotervaart
Overige ondersteuning: Stichting klinisch wetenschappelijk onderzoek Slotervaartziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

MC Slotervaart

Karin Leber
Louwesweg 6

Amsterdam 1066EC
The Netherlands
020-5125194

Wetenschappelijk

MC Slotervaart

Karin Leber
Louwesweg 6

Amsterdam 1066EC
The Netherlands
020-5125194

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known allergy for any of the study medicines

2. Pregnancy

3. In hospital patients

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-12-2016
Aantal proefpersonen:	48
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-10-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42943
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten