Patient controlled analgesia versus continuous infusion of morphine during vaso-occlusive crisis in sickle cell disease,
a randomized controlled trial.

Gepubliceerd: 12-04-2006 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON26593

Bron
NTR

Verkorte titel
N/A

Aandoening

Vaso-occlusive crisis in sickle cell disease.

Ondersteuning

Primaire sponsor: Academic Medical Center.
Department of Heamatology.
Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Pain intensity;
2. Side-effects;
3. Morphine dosage.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

To measure the efficacy of intravenous morphine administration with patient controlled analgesia compared with continuous infusion of morphine in patients with sickle cell disease (SCD) during vaso-occlusive crisis on pain, morphine dosage, and side-effects.

Design:

Non-blind randomised controlled trial.

Setting:

Tertiary referral centre.

Subjects:

Patients with SCD admitted with vaso-occlusive crisis.

Interventions:

Patient controlled analgesia (PCA-group) versus continuous infusion of morphine (CI-group).

Main outcome measures:

Pain intensity and symptoms of side-effects were measured four times per day on a 11-point numerical rating scale. Area under the curve for symptoms of side-effects during treatment, mean hourly and total morphine dosage, and mean pain score were main outcomes.

Results:

Twenty five consecutive episodes of vaso-occlusive crisis with SCD were included in the study. Patients in the PCA-group had a markedly and significant lower mean and cumulative morphine consumption as compared to those in the CI-group (0.5 mg/h versus 2.4 mg/h ($P<0.001$) and 33 mg versus 260 mg ($P=0.018$) respectively) and a non-significant reduction in the duration of hospital admission of 3 days. The mean daily pain scores were comparable (4.9 versus 5.3). The lower mean and cumulative morphine consumption in the PCA-group led to significant lower cumulative side-effect-scores for nausea and constipation during treatment compared to the CI-group (area under the curve respectively 11 versus 18 ($P= 0.045$) and 30 versus 45 ($P= 0.021$).
Conclusion Patient controlled analgesia may be first choice in morphine administration in patients admitted with vaso-occlusive crisis.

Doel van het onderzoek

The aim of our study is to determine the efficacy of PCA in vaso-occlusive crisis in patients with SCD. We will compare the effect of PCA versus standard CI morphine on cumulative morphine dose, mean daily dose and cumulative side-effects of morphine in a prospective randomized trial. In addition, quality of life and the effect on the duration of treatment and hospitalization will be determined.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patient controlled analgesia versus continuous infusion of morphine.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Sickle cell disease defined as HbSS, HbSC or HbSâ (by electropheresis);

2. Age > 17 years;

3. The presence of typical pain recognized by patients as originating from vaso-occlusive crisis and which can not be explained by other causes;

4. Severe pain necessitating treatment with intravenous morphine;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Patients already recieving opioids for more than 24 hours at time of randomization;

2. Allergy or intolerance for morphine;

3. Pregnancy;

4. Chronic use of opinoids.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	04-10-2004
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-04-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL591
NTR-old	NTR647
Ander register	: N/A
ISRCTN	ISRCTN74336585

Resultaten

Samenvatting resultaten
Am J Hematol. 2007 Nov;82(11):955-60.