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Patient controlled analgesia (PCA) versus continuous infusion (CI) of morphine during vaso-occlusive crisis in sickle cell disease (SCD): a randomised controlled trial

Submission date
28/04/2006

Recruitment status
No longer recruiting

Registration date
28/04/2006

Overall study status
Completed

Last Edited
08/09/2008

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR647

Study information

Scientific Title

Study objectives
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 randomised trial. In addition, quality of life and the effect on the duration of treatment and hospitalisation will be determined.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Non-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sickle cell disease

Interventions
Patient controlled analgesia versus continuous infusion of morphine.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Morphine

Primary outcome measure
1. Pain intensity
2. Side-effects
3. Morphine dosage

Secondary outcome measures
1. Length of treatment
2. Hospital stay
3. Quality of life

Overall study start date
04/10/2004

Completion date
14/04/2005

Eligibility

Key inclusion criteria
1. Sickle cell disease defined as HbSS, HbSC or HbSA (by electrophoresis)
2. Age greater than 17 years
3. The presence of typical pain recognised by patients as originating from vaso-occlusive crisis and which cannot be explained by other causes
4. Severe pain necessitating treatment with intravenous morphine
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Patients already receiving opioids for more than 24 hours at time of randomisation
2. Allergy or intolerance for morphine
3. Pregnancy
4. Chronic use of opioids

Date of first enrolment
04/10/2004

Date of final enrolment
14/04/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Heamatology
P.O. Box 22660
Amsterdam
Netherlands
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration