

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	☐ Prospectively registered
Registration date 28/04/2006	Overall study status Completed	☐ Protocol
Last Edited 08/09/2008	Condition category Haematological Disorders	☐ 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

Contact name

Dr B.J. Biemond

Contact details

Academic Medical Center (AMC)
Department of Clinical Chemistry
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5667391
b.j.biemond@amc.uva.nl

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Non-blind randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Length of treatment
2. Hospital stay
3. Quality of life

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration