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Use of Intravenous Paracetamol in Combination with Morphine in sickle cell disease children with vaso-occlusive crisis

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/10/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/10/2009	Haematological Disorders	[ ] 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
310

Study information

Scientific Title
Efficacy of intravenous paracetamol in combination with opiod infusion for sickle cell disease children in vaso-occlusive crisis: a single-blinded randomised trial

Acronym
IPCM

Study objectives
To look for any reduction in the amount of morphine and duration of hospitalisation as a result of using intravenous (IV) paracetamol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Medical Research and Ethics Committee of Sultan Qaboos University, Oman (ref: 310)

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sickle cell disease with vaso-occlusive crisis

Interventions
Use of IV paracetamol in combination with morphine versus use of placebo with morphine:
Group A (standard treatment): morphine (weight of the child multiplied by constant 0.5 = *mg of morphine) and placebo (50 ml of starch/dextromaltose, one hour duration, six hourly)
Group B (intervention treatment): morphine infusion and intravenous paracetamol infusion. Morphine dose is calculated as in group A, and dose of paracetamol will be 15 mg/kg/dose every six hourly in a one hour infusion.

Duration of treatment depends on the response of the pain; no standard period. The period of hospital stay will be compared later to see if there is any reduction by adding IV paracetamol to morphine treatment. The patient will have liver function tests performed at the beginning of the treatment to establish a baseline, and then the patient will be followed up in the out-patient clinic.

*mg of morphine is added to 50 ml 5% dextrose. 1 ml/hr is equal to 10 µg/kg/hr. The starting rate is 5 ml/hr which is equal to 50 µg/kg/hr. The rate is titrated according to the response of pain.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Morphine, intravenous (IV) paracetamol

Primary outcome measure
Reduction in the amount of morphine and duration of hospitalisation, assessed on a daily basis.

Secondary outcome measures
Assessed on a daily basis:
1. Reduction in duration of hospital stay (days) for pain relief
2. Reduction in pain severity on a scale of 1 - 10, which will be assessed each shift
3. Reduction of morphine requirements
4. Reduction in morphine side effects namely: prurities, nausea/vomiting, urinary retention

Overall study start date
01/05/2008

Completion date
01/05/2010

Eligibility

Key inclusion criteria
All sickle cell disease (SCD) children (aged 2 - 13 years, either sex) admitted with vaso-occlusive crisis (VOC) in B2 (blue two) ward of Sultan Qaboos University Hospital (SQUH)

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Children aged less than one year
2. Children with fever of more than 38.5°C
3. Children with prior side effects of morphine
4. Children with prior history of side effects of paracetamol
5. Children with severe jaundice or severe liver impairment

Date of first enrolment
01/05/2008

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Oman

Study participating centre
AL-Khoud
Muscat
Oman
123

Sponsor information

Organisation
Sultan Qaboos University (Oman) - College of Medicine and Health Sciences

Sponsor details
AL-Khoud
Sultanate of Oman
Muscat
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Sponsor type
University/education

Website
http://www.squ.edu.om/

ROR
https://ror.org/049xx5c95

Funder(s)

Funder type
University/education

Funder Name
Sultan Qaboos University (Oman) - College of Medicine and Health Sciences

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