

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

Submission date 28/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/10/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/10/2009	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 opioid 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

Oman

123

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