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Is intranasal fentanyl no worse than intravenous morphine in the treatment of painful sickle cell crisis in the paediatric emergency department?

Submission date
04/03/2011

Recruitment status
No longer recruiting

Registration date
01/06/2011

Overall study status
Completed

Last Edited
28/05/2020

Condition category
Haematological Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sickle cell anaemia is an inherited blood disorder which results in abnormal 'sickle' shaped red blood cells which do not fit well through small blood vessels, becoming trapped and forming blockages. Blockages prevent oxygen in the blood from reaching different parts of the body, resulting in pain. These painful crises occur commonly in children. These crises are unpredictable, affecting any area of the body, although the chest, tummy, and bones are frequently affected sites. Crises may be separated by more than a year or possibly only by weeks, and they can last from hours to weeks. Pain relief is first achieved with paracetamol or ibuprofen for milder painful episodes, but many may need stronger pain relief in the Emergency Department. Stronger pain relief may be achieved by oral medicine (codeine/morphine) and drip medicine (intravenous morphine) for moderate to severe episodes of pain. Fentanyl (another type of strong pain relief), delivered via the nose as a spray (intranasal), has been shown to be as safe and as good as morphine (via a drip) in children with broken bones or tummy pain, with the benefit of quicker time to start acting, as it does not rely on the placement of a drip. The procedure of receiving intranasal fentanyl is also less distressful for the child than a drip. The aim of this study is to assess the effect of intranasal fentanyl in painful sickle cell crisis to see whether it is as good as strong pain relief via a drip.

Who can participate?
Patients aged 1 to 21 with severe pain due to sickle cell disease

What does the study involve?
Participants are randomly allocated to be treated with either intranasal fentanyl or intravenous morphine. Pain, time to analgesic (pain relief) effect, need for more pain relief, side effects such as nausea and vomiting, breathing, heart rate and blood pressure are measured in both groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
September 2011 to June 2013

Who is funding the study?
National Children's Research Centre, Our Lady's Children's Hospital (Ireland)

Who is the main contact?
Prof. Ronan O'Sullivan
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-005161-20

ClinicalTrials.gov (NCT)
NCT03682211

Protocol serial number
08051980

Study information

Scientific Title
A randomised, controlled, double blind trial of intranasal fentanyl versus intravenous morphine in the paediatric emergency department in treatment of severe painful sickle cell crisis

Study objectives

Those patients with severe painful sickle cell crisis receiving intransala (IN) fentanyl will achieve similar pain relief to those who receive intravenous (IV) morphine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled double-blind trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Painful sickle cell crisis

Interventions
Intranasal fentanyl or intravenous morphine

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fenatanyl, morphine

Primary outcome(s)
Pain measured on an appropriate numeric pain rating scale, 10 minutes after administration of study medication

Key secondary outcome(s))
1. Time to analgesic effect: Defined as time to reduction in pain from severe to moderate/mild /no pain (pain score 0-6/10)
2. Need for rescue analgesia: defined as exacerbation of pain requiring supplemental analgesia as per the Our Ladys Childrens Hospital, Crumlin (OLCHC) clinical practice guideline
3. Other secondary effects, including:
3.1. Nausea and vomiting
3.2. Respiratory depression, defined as age-appropriate self-ventilation rate that fails to provide full ventilation and perfusion of the lungs (an oxygen saturation below 95% is deemed significant in the absence of any other aetiology other than trial medications (patients with evidence of chest involvement or chest crisis will be excluded)
3.3. Cardiovascular depression, defined as heart rate and/or blood pressure falling below age-appropriate rates in the absence of any other aetiology

3.4. Sedation level, measured using the University of Michigan Sedation Score, a 5-point scale establishing the child's level of arousal

Completion date
01/06/2013

Eligibility

Key inclusion criteria
1. Ages 1 to 21 years
2. >10kg
3. Known sickle cell disease presenting with severe pain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
21 years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Patient has received parenteral narcotic analgesic within 4 hours of emergency department (ED) presentation
2. Known allergy to fentanyl or morphine
3. Altered level of consciousness
4. Any other contraindication to opiate use
5. Blocked or traumatised nose
6. Pain not secondary to painful sickle cell crisis (PSSC)

Date of first enrolment
01/09/2011

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Dublin
Ireland
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Sponsor information

Organisation
University College Dublin (Ireland)

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Our Lady's Children's Hospital, Crumlin

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/05/2012		Yes	No
Basic results			28/05/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes