

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/05/2020	Condition category Haematological Disorders	<input type="checkbox"/> 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
ronan.osullivan@olchc.ie

Contact information

Type(s)
Scientific

Contact name
Prof Ronan O'Sullivan

Contact details
School of Medicine & Medical Science
University College Dublin
Our Lady's Children's Hospital Crumlin
Dublin
Ireland
12
+353 (0)1 409 6100/6324
ronan.osullivan@olchc.ie

Additional identifiers

EudraCT/CTIS number
2011-005161-20

IRAS number

ClinicalTrials.gov number
NCT03682211

Secondary identifying numbers
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 intranasal (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

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 to request a patient information sheet

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)

Fentanyl, morphine

Primary outcome measure

Pain measured on an appropriate numeric pain rating scale, 10 minutes after administration of study medication

Secondary outcome measures

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

Overall study start date

01/09/2011

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

Age group

Child

Lower age limit

1 Years

Upper age limit

21 Years

Sex

Both

Target number of participants

40

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

12

Sponsor information**Organisation**

University College Dublin (Ireland)

Sponsor details

Belfield

Dublin

Ireland

4

Sponsor type

University/education

Website

<http://www.ucd.ie>

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

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

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