

Ibuprofen and morphine for acute pain in sickle cell disease

Submission date 03/04/2009	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/04/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/06/2016	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=92

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00880373

Secondary identifying numbers

Study information

Scientific Title

An evaluation of the effectiveness of ibuprofen and morphine for acute pain in sickle cell disease: a double-blind, placebo-controlled randomised trial

Acronym

SWIM (Sickle With Ibuprofen and Morphine)

Study objectives

The use of oral ibuprofen combined with morphine administered through patient controlled analgesia (PCA) will be clinically effective for acute pain crisis in adults with sickle cell disease (SCD).

More details can be found at: <http://www.hta.ac.uk/1782>

Protocol can be found at: <http://www.hta.ac.uk/protocols/200700480001.pdf>

Ethics approval required

Old ethics approval format

Ethics approval(s)

London Research Ethics Committee, 27/02/2009, ref: 08/H0718/79

Study design

Double-blind placebo-controlled randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

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

Interventions

Oral ibuprofen 800 mg three times daily for a total of 2400 mg per day for 4 days. There will be a matching placebo for each active drug. Participants will be randomly allocated to one of two

treatment groups:

1. Morphine by PCA and oral ibuprofen
2. Morphine by PCA and oral placebo

Follow-up is at 1 week and 4 weeks post-discharge for both treatment groups.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ibuprofen, morphine

Primary outcome measure

PCA morphine consumption over 4 days

Secondary outcome measures

1. Rapidity of pain control - time to achieve a pain score of 4 on a standard 10-point numeric rating scale within 4 days (based on assessments of patients attending Central Middlesex Hospital)
2. Mood - measured on the Hospital Anxiety and Depression Scale (HADS)
3. Adverse opioid effects - including nausea, constipation, itching, and central nervous system effects
4. Other sickle cell complications - including neurological events, and acute chest syndrome
5. Use of blood transfusions - treatment for complications during or post-discharge study period of 4 weeks
6. Health service utilisation cost - length of hospital admission, and re-admission in 7 - 14 days
7. Quality of life and utility - measured on the EuroQol (EQ-5D)
8. Patient satisfaction - patient experience at discharge

Overall study start date

01/09/2009

Completion date

31/08/2013

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Adult patients with SCD of any phenotype and gender aged 16 years and over.

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

320

Key exclusion criteria

1. Patient has a history of allergic reaction to either morphine or ibuprofen
2. Patient has contraindications to morphine or ibuprofen, e.g. peptic ulcer disease, non-steroidal anti-inflammatory drug (NSAID)-induced asthma
3. Patient in a drug dependency programme
4. Patient is on renal dialysis
5. Stroke within the last 6 weeks
6. Platelet count less than $50 \times 10^9/l$
7. Patient is pregnant or breastfeeding
8. Doctor unwilling to randomise the patient for other reasons
9. Previous participation in the trial

Date of first enrolment

01/09/2009

Date of final enrolment

31/08/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

North West London Hospitals NHS Trust

London

United Kingdom

NW10 7NS

Sponsor information

Organisation

North West London Hospitals NHS Trust (UK)

Sponsor details

Research and Development
Northwick Park Hospital
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Middlesex
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HA1 3UJ
+44 (0)20 8869 2011
Research@nwlh.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.nwlh.nhs.uk>

ROR

<https://ror.org/04cntmc13>

Funder(s)**Funder type**

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Other publications	why trial was stopped:	09/06/2016		Yes	No
HRA research summary			28/06/2023	No	No