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Ibuprofen and morphine for acute pain in sickle cell disease

Submission date 03/04/2009	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/04/2009	**Overall study status** Stopped	
Last Edited 13/06/2016	**Condition category** Haematological Disorders	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=92

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00880373

Secondary identifying numbers

HTA 07/48/01

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 x 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)

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Research and Development
Northwick Park Hospital
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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