ISRCTN25343280 https://doi.org/10.1186/ISRCTN25343280

Patient controlled analgesia (PCA) versus routine care in the Emergency Department

Submission date	Recruitment status	[X] Prospectively registered
04/07/2011	No longer recruiting	[X] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
04/07/2011	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
15/08/2016	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Background and study aims
Pain is very common in patients attending Emergency (A&E) Departments. Pain is sometimes difficult to treat, and individual patient satisfaction and levels of pain control also vary. In recent national surveys more than half of patients felt more could be done to treat their pain during their attendance. Normally when a patient is in severe pain in the Emergency Department they receive morphine, a strong painkiller, through a drip. Nurses give the injection, and then return after a while to see if any further treatment is needed. This might involve further doses of morphine or other types of painkiller if more appropriate. When they are admitted to a ward, it is more common for patients to be prescribed painkillers taken by mouth. A patient-controlled analgesia (PCA) device is a syringe that can be connected to a drip in the patients arm, which allows the patient to deliver their own painkiller into a vein by pressing a button attached to the syringe holder. It has a safety device to prevent too much drug being delivered. PCAs are commonly used in a variety of different settings in the hospital (typically after an operation), but they are not usually used for emergency patients. This study aims to see if giving patients a PCA machine in the Emergency Department, and during the first few hours of their stay in hospital, improves pain relief and satisfaction.

Who can participate?
Patients aged between 18 and 75 with traumatic injuries or non-traumatic abdominal pain.

What does the study involve?
Patients who agree to take part will be randomly allocated to receive either PCA or standard treatment involving nurses giving pain relief drugs then returning after a period of time to see whether any further medication is required. In addition, all patients in the study will be offered other forms of painkillers as necessary. By using the two methods of administration we will be able to assess whether there is benefit in terms of pain control and satisfaction with treatment between the two methods of managing pain.

What are the possible benefits and risks of participating?
We feel that by giving patients control of their own pain relief, they may feel their pain is better managed.

Where is the study run from?
Derriford Hospital, Plymouth (UK)

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

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Jason Smith
jasonesmith@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Jason Smith

Contact details
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH
-
jasonesmith@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10515

Study information

Scientific Title
An open randomised trial of patient controlled analgesia (PCA) versus routine care in the Emergency Department

Acronym
PAin SoluTions In the Emergency Setting (PASTIES)

Study objectives
Pain is an extremely common presentation to Emergency Departments (EDs), but is often difficult to treat effectively (almost half of patients recently surveyed thought more could be done to treat their pain in the ED). Routine treatment of severe pain involves intermittent doses of intravenous morphine, administered by nurses.

Patient controlled analgesia (PCA) is effective in many clinical settings, but there is very little evidence relating to its use in the ED. No previous study has investigated the issue of continuing a PCA from the emergency department and during the first few hours of a patient's admission to hospital, to optimise their pain relief.

The aim of this study is to compare PCA with routine care (nurse-titrated analgesia) in adult emergency patients who present to the Emergency Department in severe pain from traumatic injuries or non-traumatic abdominal pain, and are then admitted to an inpatient ward. We plan to undertake a non-blinded randomised trial of PCA versus routine care in these patients. The primary outcome is a selfadministered visual analogue scale pain score, completed hourly for 12 hours. Secondary outcomes include total opioid dose and other analgesic use, adverse effects, and patient satisfaction. An economic evaluation will compare PCA with standard care in a cost-effectiveness analysis.

Added 31/03/2014: The study is conceived as two distinct trials within one study protocol, having been powered separately for the two different populations of patients; the results will accordingly be analysed and presented separately.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central REC (Southampton), May 2011, ref: 11/SC/0151

Study design
Randomised; Interventional; Design type: Not specified, Treatment

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

Topic: Injuries and Emergencies; Subtopic: Injuries and Emergencies (all Subtopics); Disease: Injuries and Emergencies

Interventions
Number of participants in each group - 400 total, i.e. 200 with non-traumatic abdominal pain and 200 with musculoskeletal injury, half of whom will receive PCA and half will receive standard care.

Patients will be randomised to either standard care involving bolus intravenous (IV) morphine and multimodal analgesia, or PCA. PCA is maximum 1mg morphine per 5 minutes with lock out on PCA device.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine

Primary outcome measure
Visual Analogue Scale (VAS) Pain Score; Timepoint(s): hourly for 12 hours

Secondary outcome measures
1. Total opioid dose and use of other analgesics
2. Opioid side-effects
3. Patient satisfaction with pain management
4. Proportion of study period with VAS >44mm
5. Proportion of study period spent sleeping
6. Length of hospital stay
7. Incremental cost effectiveness ratio (ICER)

Overall study start date
04/07/2011

Completion date
03/01/2013

Eligibility

Key inclusion criteria
1. Adult patients aged between 18 and 75 years of age inclusive
2. Traumatic injuries or non-traumatic abdominal pain
3. In severe pain on arrival in the Emergency Department
4. Admission to hospital is intended at the time of enrolment
5. Provision of informed consent to participate.; Target Gender: Male & Female; Upper Age Limit 75 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Key exclusion criteria
1. Patients over 75 years
2. Patients with a reduced conscious level
3. Inability to operate a PCA device
4. Patients who cannot understand the study information (e.g. due to pre-existing dementia, learning difficulties, or intoxication)
5. Patients with chronic pain
6. Patients who are opioid tolerant
7. Patients with active opioid addiction
8. Patients with a history of renal failure
9. Allergy or other contraindication to morphine
10. Hypotension (systolic blood pressure <90mmHg)
11. Patients in police custody, or prisoners
12. Inability to gain intarvenous (IV) access
13. Patients who are likely to be definitively treated in the ED and discharged
14. Patients who are pregnant or breastfeeding
15. Open fractures (excluded because this group of patients will undergo surgery within six hours of injury according to national standards)
16. Patients on other predetermined analgesia pathway (e.g. regional anaesthesia)
17. Previous participation in this study
18. Current participation in another Clinical Trial of an Investigational Medicinal Product (CTIMP)

Date of first enrolment
04/07/2011

Date of final enrolment
03/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

Sponsor details
Derriford Hospital
Derriford Road
Plymouth
England
United Kingdom
PL6 8DH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

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	14/02/2013		Yes	No
Results article	results	21/06/2015		Yes	No
Results article	results	21/06/2015		Yes	No
HRA research summary			28/06/2023	No	No