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Pethidine versus Diamorphine Study

Submission date
12/05/2010

Recruitment status
No longer recruiting

Registration date
12/05/2010

Overall study status
Completed

Last Edited
17/04/2014

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6895

Study information

Scientific Title

A two centre randomised controlled trial comparing intramuscular diamorphine and intramuscular pethidine for labour analgesia

Acronym
IDvIP

Study objectives
Study objectives:
To evaluate the maternal and neonatal efficacy and safety of intramuscular diamorphine 7.5 mg versus intramuscular pethidine 150 mg for labour pain.

Evaluation of study:
An intention to treat analysis will be used. Results will be presented with 95% confidence intervals whenever possible and will be reported using CONSORT guidelines.

Duration of study period: 3 years

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and SW Hampshire REC (B) approved on the 2nd March 2007 (ref: 07/Q1704/6)

Study design
Multicentre randomised process of care cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

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: Reproductive Health and Childb, Generic Health Relevance and Cross Cutting Themes, Primary Care Research Network for England; Subtopic: Not Assigned, Reproductive Health and Childb (all Subtopics), Generic Health Relevance (all Subtopics); Disease:

Interventions

Study Medicinal Products: 7.5 mg diamorphine and 150 mg pethidine up to a maximum of two doses with a minimal interval of 2 hours between doses. Total duration of treatment and follow-up will be the duration of the womens labour plus 24 hours after birth.

As of 10/01/2011 this record was updated to include an extended anticipated end date; the initial anticipated end date was 01/05/2010.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Pethidine, diamorphine

Primary outcome measure
1. Change in pain intensity over 3 hours (AUC)
2. Side effects:
2.1. Need for neonatal resuscitation
2.2. Apgar score less than 7 at 1 minute

Secondary outcome measures
1. Pain relief
2. Maternal sedation
3. Nausea and vomiting
4. CTG
5. Patient satisfaction
6. % choosing analgesia for next pregnancy
7. Meconium staining
8. UApH
9. UVpH
10. Apgar scores
11. Naloxone
12. Neonatal SpO2
13. Feeding behaviour

Overall study start date
01/11/2008

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Active labour with a singleton pregnancy
2. Regular uterine contractions of at least two in 10 minutes
3. Cervical dilatation of at least 3 cm
4. Foetal gestational age of 37 - 42 weeks

5. Minimum weight of 60 kg
6. Multiparous and nulliparous women
7. Spontaneously gone into labour or have had an amniotomy and intravenous oxytocin to induce labour
8. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned sample size: 450

Key exclusion criteria
1. Allergy or previous severe reaction to opioid analgesia
2. Opioid dependency
3. History of foetal compromise
4. Maternal cardiorespiratory compromise
5. American Society of Anaesthesiologists (ASA) grade 3 and 4
6. Maternal weight greater than 120 kg

Date of first enrolment
01/11/2008

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Poole Hospital NHS Foundation Trust
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

Sponsor details
St Mary's Maternity Hospital
Longfleet Road
Poole
England
United Kingdom
BH15 2JB

Sponsor type
Hospital/treatment centre

Website
http://www.poole.nhs.uk

ROR
https://ror.org/03kdm3q80

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	08/07/2011		Yes	No
Results article	results	01/03/2014		Yes	No