# Pethidine versus Diamorphine Study

[ ] Prospectively registered Submission date Recruitment status 12/05/2010 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 12/05/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category 17/04/2014 Pregnancy and Childbirth

#### Plain English summary of protocol

Not provided at time of registration

### Contact information

#### Type(s)

Scientific

#### Contact name

Miss Dawn Jackson

#### Contact details

Poole Hospital NHS Foundation Trust St Mary's Maternity Hospital Poole United Kingdom BH15 2JB

## Additional identifiers

Protocol serial number 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

#### Study type(s)

Quality of life

#### 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(s)

- 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

#### Key secondary outcome(s))

- 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

#### 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

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

Sex

#### Female

#### 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

**United Kingdom** 

**England** 

Study participating centre Poole Hospital NHS Foundation Trust

Poole United Kingdom BH15 2JB

## Sponsor information

#### Organisation

Poole Hospital NHS Foundation Trust (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**

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?
Results article	results	01/03/2014	Yes	No
<u>Protocol article</u>	protocol	08/07/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes