

# The effect of emulsion formulation on Propofol injection pain

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2009	<b>Condition category</b> Surgery	<input type="checkbox"/> 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**  
N0244124360

## Study information

## **Scientific Title**

### **Study objectives**

Does Propofol Lipuro cause less injection pain than standard Propofol obviating the need to add Lidocaine local anaesthetic?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised double blind controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Other

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Surgery: Anaesthesia

### **Interventions**

Patients were allocated randomly into two groups to receive either Propofol-Lipuro without added lidocaine or Diprivan mixed with lidocaine 10 mg.

5 ml of the study solution was injected at a constant rate over 15 s and patients graded any associated pain or discomfort using a four-point verbal rating scale.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Specified

### **Primary outcome measure**

Injection pain experienced by patients during induction of general anaesthesia

### **Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/05/2003

**Completion date**

30/04/2004

## Eligibility

**Key inclusion criteria**

Patients scheduled for surgery requiring general anaesthesia in whom Propofol is an appropriate anaesthetic induction agent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

200

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/05/2003

**Date of final enrolment**

30/04/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Birch House

Stockport

United Kingdom

SK2 7JE

# Sponsor information

## Organisation

Department of Health

## Sponsor details

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Stockport NHS Trust (UK)

# 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?
<a href="#">Results article</a>	results	01/12/2004		Yes	No