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The effect of emulsion formulation on Propofol injection pain

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2009	Surgery	

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?
Results article	results	01/12/2004		Yes	No