ISRCTN10285854 https://doi.org/10.1186/ISRCTN10285854

A randomised double-blind comparative trial investigating the level of pain experienced on induction of anaesthesia using either standard Propofol 1% or Propofol-Lipuro 1% with or without the addition of lignocaine 2% (1:10 ratio)

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
05/09/2012

Condition category
Surgery

[_] Prospectively registered
[_] 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

Contact name
Dr A Mallick

Contact details
Anaesthetics
D Floor, Jubilee Building
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 243 2799
Abhiram.Mallick@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436125555

Study information

Scientific Title

Study objectives
To determine which propofol preparation affords the least pain on injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind comparative trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
1. Standard Therapy
2. New Therapy

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Standard Propofol 1% or Propofol-Lipuro 1% with or without the addition of lignocaine 2%

Primary outcome measure
Injection pain/no pain comparison between groups

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2003

Completion date
01/04/2006

Eligibility

Key inclusion criteria
Patients undergoing uncomplicated elective surgery

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2003

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetics
Leeds
United Kingdom
LS1 3EX

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
Government

Funder Name
Leeds Teaching Hospitals 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	01/05/2007		Yes	No