



Clinical trial results:

Effect site controlled, reaction time safeguarded, patient maintained sedation with Propofol

- A) in oral surgery patients**
- B) in general dentistry patients**
- C) in colonoscopy patients**

Summary

EudraCT number	2005-005758-39
Trial protocol	GB
Global end of trial date	11 February 2011

Results information

Result version number	v1 (current)
This version publication date	13 April 2019
First version publication date	13 April 2019
Summary attachment (see zip file)	2005-005758-39 summary (2005-005758-39 summary.pdf)

Trial information

Trial identification

Sponsor protocol code	9812/A
-----------------------	--------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Sponsor reference: WN06AN024

Notes:

Sponsors

Sponsor organisation name	NHS Greater Glasgow and Clyde
Sponsor organisation address	Clinical Research & Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, United Kingdom, G3 8SW
Public contact	Dr Debra Stuart, NHS Greater Glasgow and Clyde, debra.stuart@glasgow.ac.uk
Scientific contact	Dr Debra Stuart, NHS Greater Glasgow and Clyde, debra.stuart@glasgow.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 April 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 February 2011
Global end of trial reached?	Yes
Global end of trial date	11 February 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess whether patient-maintained sedation (the patient controls his/her degree of sedation using a hand-held device) using the drug propofol is safer and more effective when using deteriorating reaction time as an added safeguard against the potential for oversedation in groups of patients undergoing dental surgery and colonoscopy.

Protection of trial subjects:

The routine use of propofol traditionally is restricted to anaesthetists, as in high doses general anaesthesia is produced with possible loss of airway patency. Currently the safety feature is predominantly that as patients become more sedated they cannot press the patient demand button and hence cannot increase the amount of propofol they are receiving. Also the device ensures that the blood and brain concentrations have equilibrated to within 10% of each other before another successful demand for propofol can be made (usually takes approximately two minutes) and it only allows a maximum calculated brain concentration of 3 micrograms/milliliter of propofol. The device also will start to decrease the calculated brain concentration of propofol if the demand button has not been pressed for six minutes.

Background therapy:

N/A

Evidence for comparator:

N/A

Actual start date of recruitment	06 December 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy patients (ASA physical status 1-2) receiving sedation while undergoing oral surgery recruited via NHS clinics in the United Kingdom

Pre-assignment

Screening details:

Inclusion Criteria

ASA I-II (healthy or only mild systemic illness) undergoing planned dental surgery or colonoscopy; Age 18-65yrs

Exclusion Criteria

ASA III or above; Outwith age group above; Contraindication to Propofol; History of epilepsy; History of substance abuse; Major Psychiatric illness; Pregnancy or breastfeeding; Unable to consent

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

n/a

Arms

Arm title	Oral Surgery
-----------	--------------

Arm description:

oral surgery patients

Arm type	Experimental
Investigational medicinal product name	Propofol
Investigational medicinal product code	
Other name	Diprivan
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

1% = 10mg/ml. Target Controlled Infusion (50ml prefilled syringe)

Number of subjects in period 1	Oral Surgery
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Oral Surgery
-----------------------	--------------

Reporting group description:

oral surgery patients

Reporting group values	Oral Surgery	Total	
Number of subjects	20	20	
Age categorical			
Adults			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	35.0		
standard deviation	± 14.7	-	
Gender categorical			
Units: Subjects			
Female	17	17	
Male	3	3	
Weight			
Units: kg			
arithmetic mean	72.6		
standard deviation	± 14.7	-	

End points

End points reporting groups

Reporting group title	Oral Surgery
Reporting group description: oral surgery patients	

Primary: Minimal sedation level

End point title	Minimal sedation level ^[1]
End point description: Observer's Assessment of Alertness Sedation score Range: 1 (unresponsive) to 5 (fully awake)	
End point type	Primary
End point timeframe: Treatment period	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Pilot single group, prospective, phase IV study; no formal statistical analysis performed. Descriptive statistics only reported.

End point values	Oral Surgery			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: number				
score 1	0			
score 2	0			
score 3	0			
score 4	9			
score 5	11			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Time for sedation

End point title	Time for sedation
End point description:	
End point type	Post-hoc
End point timeframe: Treatment period	

End point values	Oral Surgery			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: minutes				
arithmetic mean (standard deviation)	25 ($\pm$ 11)			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Maximum propofol effect-site concentration

End point title	Maximum propofol effect-site concentration
End point description:	
End point type	Post-hoc
End point timeframe:	
Treatment period	

End point values	Oral Surgery			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: microgram(s)/millilitre				
arithmetic mean (standard deviation)	1.6 ($\pm$ 0.5)			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Lowest oxygen saturation

End point title	Lowest oxygen saturation
End point description:	
End point type	Post-hoc
End point timeframe:	
Treatment period	

End point values	Oral Surgery			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: SaO2%				
arithmetic mean (standard deviation)	98.0 (± 2.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Initiation of sedation to discharge following the surgical procedure.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	17
--------------------	----

Reporting groups

Reporting group title	Participant group
-----------------------	-------------------

Reporting group description: -

Serious adverse events	Participant group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Participant group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No adverse events were reported, confirmed by the PI to the CI on 22/08/2007

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 August 2008	Change of Chief Investigator

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/24044388>