

Evaluation of nitrous oxide treatment given to children with procedural problems - a comparison with midazolam and the release of hormones

Submission date 28/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/09/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Claude Marcus

Contact details
Division of Pediatrics, CLINTEC
Karolinska Institutet
Division of Endocrinology, Diabetes and Metabolism
National Childhood Obesity Centre
Karolinska University Hospital
Stockholm
Sweden
14186
claude.marcus@ki.se

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Evaluation of nitrous oxide treatment given to children with procedural problems - a comparison with midazolam and the release of hormones: a prospective double-blind randomised study

Study objectives

Is nitrous oxide treatment improving patient care in the out-patient paediatric departments compared to midazolam?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of South Stockholm gave approval on the 14th January 2005 (ref: 050114)

Study design

Prospective double-blind randomised study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Difficulties establishing intravenous access

Interventions

Evaluation of nitrous oxide treatment and midazolam given to children with procedural problems, comparing three different methods of treatment:

1. Midazolam 0.3 mg/kg maximum 15 mg per os oxygen for inhalation (n = 30)
2. 50% nitrous oxide 50% oxygen for inhalation (n = 30)
3. 10% nitrous oxide (placebo) 90 % oxygen (n = 30)

All 90 children had 15 ml syrup with or without midazolam and after 40 minutes all children were breathing into a mask with or without nitrous 3 minutes before, during and 3 minutes after venous cannulation. All children were followed up at least 4 hour after the treatments.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Nitrous oxide, midazolam

Primary outcome(s)

1. Number of attempts that were required for double venous cannulation (number), 15 minutes after procedure
2. Child evaluation (Global Rating Scale GRS 1 - 5, where 1 = poor and 5 = excellent) recovery time (minutes), measured by finger tapping test 40 minutes before procedure and 15 minutes after procedure and if necessary every 15 minutes until the child had the same number of finger taps as before the procedure

Key secondary outcome(s)

1. Pain (Numeric Rating Scale [NRS] 0 - 10, where 0 = no pain and 10 = worst pain), evaluation by parent 15 minutes after procedure
2. Observer's Assessment of Alertness Sedation (OAA/S) scale 0 - 1, where 0 = deep asleep and 5 = alert), measured 30 minutes after procedure
3. Blood pressure, measured 40 minutes before the procedure, every 5 minutes during procedure, and 15 minutes after procedure and if necessary every 15 minutes after this
4. Heart rate, measured 40 minutes before the procedure, every 5 minutes during procedure, and 15 minutes after procedure and if necessary every 15 minutes after this
5. Saturation, measured 40 minutes before the procedure, every 5 minutes during procedure, and 15 minutes after procedure and if necessary every 15 minutes after this
6. Side effects, measured 40 minutes before the procedure, every 5 minutes during procedure, and 15 minutes after procedure and if necessary every 15 minutes after this

Completion date

30/12/2008

Eligibility

Key inclusion criteria

Children (aged 5 - 18 years, either gender) with well known difficulties to establish intravenous access.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. No ability to collaborate
2. Mental disturbance
3. Not fluent in Swedish

Date of first enrolment

01/04/2005

Date of final enrolment

30/12/2008

Locations

Countries of recruitment

Sweden

Study participating centre

Division of Pediatrics, CLINTEC

Stockholm

Sweden

14186

Sponsor information

Organisation

Frimurare Barnhuset Foundation (Stiftelsen Frimurare Barnhuset i Stockholm) (Sweden)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Childrens Hospital Karolinska University Hospital Huddinge Stockholm (Sweden)

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	01/09/2011		Yes	No
Results article	results	01/09/2012		Yes	No