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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/01/2009	**Overall study status** Completed	
Last Edited 24/09/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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