Paediatric i-gel™ laryngeal masks compared with the Ambu Aura Once™ laryngeal mask

Submission date	Recruitment status	Prospectively registered
24/08/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
11/11/2009	Completed	Results
Last Edited	Condition category	Individual participant data
11/11/2009	Respiratory	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers KEK018/08

Study information

Scientific Title

Comparison of the laryngeal mask airway Ambu Aura Once™ and the i-gel™ in elective anaesthetised and ventilated paediatric patients

Acronym

Paediatric i-gel

Study objectives

H0 = Mean Airway seal pressure Ambu ≥ Mean Airway seal pressure i-gel.

H1 = Mean Airway seal pressure Ambu < Mean Airway seal pressure i-gel.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Berne, approved on 02/02/2009 (ref: 018/09)

Study design

Prospective randomised gold-standard controlled single-blinded (patient) trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (in German)

Health condition(s) or problem(s) studied

Airway management in paediatric patients

Interventions

According to randomisation, patients will be ventilated by either one of the masks involved in the study: either the paediatric sized i-gel™ or the paediatric sized Ambu Aura Once™. No other interventions.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Oropharyngeal leak pressure

Secondary outcome measures

- 1. First attempt success rate
- 2. Time necessary for completion of first attempt
- 3. Insertion success of a gastric catheter
- 4. Fiberoptic laryngeal view
- 5. Adverse events

Overall study start date

15/08/2009

Completion date

15/08/2010

Eligibility

Key inclusion criteria

- 1. Patients of both genders, aged 0-17 years
- 2. Weight of 5-50 kg
- 3. American Society of Anaesthesiologists (ASA) physical status I-II
- 4. Scheduled at the University Hospital of Bern for elective surgery planned for general anaesthesia not requiring tracheal intubation

Participant type(s)

Patient

Age group

Child

Upper age limit

17 Years

Sex

Both

Target number of participants

240

Key exclusion criteria

- 1. Planned operation time >4h
- 2. Risk of aspiration (non-fasted, massive gastroesophageal reflux disease, gastrointestinal stenosis or stricture)
- 3. Known difficult airway (difficult mask ventilation or difficult laryngoscopy, Cormack-Lehane grade >2)
- 4. Congenital malformations involving the respiratory tract
- 5. Cervical spine disease
- 6. Upper respiratory tract symptoms in the previous 14 days
- 7. Preoperative sore throat
- 8. Patients with non-German-speaking parents or refusing to participate

Date of first enrolment

15/08/2009

Date of final enrolment

15/08/2010

Locations

Countries of recruitment

Switzerland

Study participating centre Inselspital, University Hospital Bern

Bern Switzerland CH-3010

Sponsor information

Organisation

Inselspital, University Hospital Bern (Switzerland)

Sponsor details

Department of Anesthesiology Bern Switzerland CH-3010 +41 (0)31 632 2111 robert.greif@insel.ch

Sponsor type

Hospital/treatment centre

Website

http://www.anaesthesie.insel.ch

ROR

https://ror.org/01q9sj412

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Inselspital, University Hospital Bern (Switzerland), Departmental Research Fund

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration