ISRCTN64997093 https://doi.org/10.1186/ISRCTN64997093

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

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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
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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 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