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Effect of dexamethason on the incidence of detubation failure in children

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2021	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

Study information

Scientific Title
Effect of dexamethason on the incidence of detubation failure in children

Study objectives
Dexamethason reduces the rate of detubation failure in children at risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo controlled, parallel group, double blinded multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mechanical ventilation, complications

Interventions
Intervention: Dexamethason 6 x 0.5 mg/kg intravenous (i.v.) every six hours (max 10 mg dose) first dose six to 12 hours prior to detubation.
Placebo: Saline (NaCl 0.9%)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dexamethason

Primary outcome(s)
Detubation failure

Key secondary outcome(s))
1. Use of other therapies to reduce upper airway obstruction (epinephrin, beclomethasone)
2. Croup score
3. Supplemental oxygen
4. Adverse effects of dexamethason: hypertension, gastro-intestinal tract bleeding, hyperglycaemia

Completion date
01/04/2006

Eligibility

Key inclusion criteria

1. Aged four weeks to four years
2. Intubated more than 24 hours
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 weeks

Upper age limit
4 years

Sex
Not Specified

Key exclusion criteria
1. Known with one of the following diseases:
a. peptic ulcurs
b. diabetes mellitus
c. osteoporosis
d. adrenal insufficiency
e. hypertension
f. systemic yeast infection
g. tuberculosis
h. sepsis
2. Glucocorticoid use the week before detubation
3. Intubation for laryngotracheal infection
4. Mechanical ventilation for upper airway obstruction
5. Down syndrome

Date of first enrolment
01/01/2004

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Fellow of pediatric intensive care
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (The Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration