Effect of dexamethason on the incidence of detubation failure in children.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28763

Source
NTR

Brief title
N/A

Health condition

Mechanically ventilated children.

Sponsors and support

Primary sponsor: Department of pediatrics
VU University Medical Center
Postbus 7057
1007 MB Amsterdam
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Detubation failure.

Secondary outcome

1. Use of other therapies to reduce upper airway obstruction (epinephrin, beclomethasone);

2. Croup score;

3. Supplemental oxygen;

4. Adverse effects of dexamethason: hypertension, Gatro-intestinal tract bleeding, hyperglycaemia.

Study description

Background summary

Upper airway obstrection is frequently seen (30%) after detubation in children at risk (4 weeks-4years, and prolonged intabation > 24 hours). There is often a need for reintubation (5%). Dexamethason may reduce the the frequency of upper airway obstruction and the need for reintubation. This has been studied earlier, however there is a lack of properly designed studies.

Study objective

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

Study design

N/A

Intervention

Dexamethason 6 x 0,5 mg/kg i.v. à 6 uur (max 10 mg dose) first dose 6 - 12 hours prior to detubation.

Placebo: Saline (NaCl 0,9%).

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 4 weeks - 4 years;

2. Intubated > 24 hours;

3. Informed consent.

Exclusion criteria

1. Known with one of the following diseases:

a. peptic ulcus;

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2004
Enrollment:	157
Type:	Actual

Ethics review

Positive opinion

Date:	24-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL110
NTR-old	NTR141
Other	: N/A
ISRCTN	ISRCTN54608329

Study results

Summary results
N/A