ISRCTN54608329 https://doi.org/10.1186/ISRCTN54608329

Effect of dexamethason on the incidence of detubation failure in children

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M. van Heerde

Contact details
Fellow of pediatric intensive care
VU University Medical Centre
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 4426/3000
m.vanheerde@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Detubation failure

Secondary outcome measures
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

Overall study start date
01/01/2004

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

Age group
Child

Lower age limit
4 Weeks

Upper age limit
4 Years

Sex
Not Specified

Target number of participants
157

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)

Sponsor details
Department of Paediatrics/Neonatology
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV
+31 (0)20 444 4444
w.fetter@vumc.nl

Sponsor type
University/education

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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