ISRCTN13421709 https://doi.org/10.1186/ISRCTN13421709

The efficacy of dexamethasone in mechanically ventilated children with lower respiratory tract infection caused by respiratory syncytial virus (RSV)

Submission date
29/11/2005

Recruitment status
No longer recruiting

Registration date
01/12/2005

Overall study status
Completed

Last Edited
11/10/2011

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Job van Woensel

Contact details
Pediatric Intensive Care Unit G8ZW
Emma Children's Hospital/AMC
Amsterdam
Netherlands
1100 DD

Additional identifiers

Protocol serial number
Protocol 5/5

Study information

Scientific Title

Acronym
STAR-trial

Study objectives
Does dexamethasone shorten the duration of mechanical ventilation in children with RSV lower respiratory tract infection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved Medical Ethics Committee, Academic Medical Center, Amsterdam, The Netherlands. Date of approval: 24/11/2003. Reference number: MEC 03/079 # 03.17.0538c.

Primary study design
Interventional

Study design
Multicenter double-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory syncytial virus lower respiratory tract infection

Interventions
Dexamethasone 0.15 mg/kg/dose every 6 hours, 8 doses in total (i.e. 2 days) or placebo (normal saline)

2004 protocol version 5/5 in http://www.star-trial.com/files/STARprotocol_aug04.pdf

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Duration of mechanical ventilation

Key secondary outcome(s)
1. Length of stay in paediatric intensive care unit (PICU)
2. Length of stay in hospital
3. Duration of supplemental oxygen therapy

Completion date

01/04/2007

Eligibility

Key inclusion criteria
1. Children younger than 2 years of age
2. Microbiologically proven RSV lower respiratory tract infection
3. Mechanical ventilation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
2 Years

Sex
All

Key exclusion criteria
1. Corticosteroid use within 2 weeks before inclusion
2. No informed consent from parents or caretakers

Date of first enrolment
01/11/2003

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Pediatric Intensive Care Unit G8ZW
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Main source: Academic Medical Center, Amsterdam, The Netherlands

Funder Name
Secondary sources:

Funder Name
1 Van Reekum - van Moorselaar foundation, Amsterdam, The Netherlands

Funder Name
2 Johannes Foundation, Rotterdam, The Netherlands

Funder Name
3 Maarten Kappelle Foundation, Voorburg, The Netherlands

Funder Name
4 IVAX Farma B.V. Bodegraven, The Netherlands

Funder Name
5 Draeger Medical Netherlands BV Zoetermeer, The Netherlands

Funder Name
6 Arrow Holland Medical Products B.V. Weesp, The Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes