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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/12/2005	**Overall study status** Completed	
Last Edited 11/10/2011	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.star-trial.com

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Multicenter double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Duration of mechanical ventilation

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

Overall study start date
01/11/2003

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

Age group
Child

Upper age limit
2 Years

Sex
Both

Target number of participants
230

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)

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5669111
ic.kinderen@amc.nl

Sponsor type
University/education

Website
http://www.amc.nl

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

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

Study outputs

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