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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
29/11/2005		☐ Protocol		
Registration date 01/12/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 11/10/2011	Condition category Respiratory	[] Individual participant data		

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

Dr Job van Woensel

Contact details

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

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 summaryNot 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