

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
Registration date 01/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/10/2011	Condition category Respiratory	☐ 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.

Study design

Multicenter double-blind randomised controlled trial

Primary study design

Interventional

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