

Efficacy of inhaled DNase in admitted infants with RSV-bronchiolitis

Submission date 12/09/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 12/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/08/2009	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR82

Study information

Scientific Title

Study objectives

Nebulised DNase has a decreasing effect on the duration of a hospital admission in infants admitted with an RSV-bronchiolitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised double blind placebo controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bronchiolitis, RSV-bronchiolitis

Interventions

Twice daily 2.5 mg DNase or placebo during admission.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Length of stay
2. Symptom score

Key secondary outcome(s)

1. Duration of oxygen supplementation
2. Need for ICU-admission

Completion date

01/04/2006

Eligibility**Key inclusion criteria**

1. RSV bronchiolitis with need for additional oxygen (saturation $\leq$ 92 %)
2. RSV-infection proven with rapid assay or culture
3. Age < 12 months
4. Admission on (medium care) ward
5. Study medication can be started within 24 hours

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Premature birth (born < 32 weeks of gestation)
2. Congenital heart disease
3. Pre-existent lung disease (e.g. BPD or CF)
4. T-cell immune deficiency
5. Pre-treatment with systemic steroids

Date of first enrolment

01/01/2006

Date of final enrolment

01/04/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Erasmus MC Sophia Children's Hospital

Rotterdam

Netherlands

3000 CB

Sponsor information**Organisation**

Roche Nederland BV (Netherlands)

ROR

<https://ror.org/01gcg9888>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (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	01/03/2007		Yes	No