ISRCTN92577199 https://doi.org/10.1186/ISRCTN92577199

Efficacy of inhaled DNase in admitted infants with RSV-bronchiolitis

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R Boogaard

Contact details
Erasmus MC Sophia Children's Hospital
Researcher Pediatric Pulmonology Department
Room SB-2666
P.O.Box 2060
Rotterdam
Netherlands
3000 CB
+31 (0)10 4636683
r.boogaard@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre randomised double blind placebo controlled parallel group 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
Bronchiolitis, RSV-bronchiolitis

Interventions
Twice daily 2.5 mg DNase or placebo during admission.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Length of stay
2. Symptom score

Secondary outcome measures

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

Overall study start date
01/01/2006

Completion date
01/04/2006

Eligibility

Key inclusion criteria
1. RSV bronchiolitis with need for additional oxygen (saturation iÜ 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

Age group
Other

Sex
Both

Target number of participants
222 (added 25/08/09)

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-cel 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)

Sponsor details
Postbus 44
Woerden
Netherlands
3440 AA

Sponsor type
Industry

ROR
https://ror.org/01gcg9888

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (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	01/03/2007		Yes	No