ISRCTN73641710 https://doi.org/10.1186/ISRCTN73641710

# Effect of palivizumab on wheezing after respiratory syncytial virus (RSV) infection

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 21/11/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/01/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/03/2020 | Respiratory | |

## Plain English summary of protocol

Background and study aims
Respiratory syncytial virus (RSV) is a very common virus that leads to mild, cold-like symptoms in adults and older healthy children. It is not known whether recurrent wheezing in preterm children is caused by RSV infection, or whether RSV infection is just the first indication of chronic airway disease that would develop anyway. This study aims to find out by investigating whether prevention of RSV using the drug palivizumab results in a decreased incidence of recurrent wheeze.

Who can participate?
Healthy preterm infants (gestational age between 32 and 35 weeks)

What does the study involve?
Infants are randomly allocated to receive one-monthly intramuscular injections (into a muscle) of either palivizumab or a placebo (dummy) drug from discharge until the end of the RSV season, with a maximum of five injections. Number of wheezing days are recorded during the first year of life, and questionnaires are completed at age 1, 3 and 6 years. Throat swabs are taken for viral analysis during the RSV season in case of a runny nose or mild cough. These samples are tested for viruses, to determine whether the child is infected with RSV and/or other viruses. Lung function is tested and asthma-related breathing symptoms are measured by questionnaire at age 6 years.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Medical Centre Utrecht (UMCU) (Netherlands)

When is the study starting and how long is it expected to run for?
August 2008 to April 2017

Who is funding the study?
Abbott International plc (UK)

Who is the main contact?
Dr Louis Bont
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Louis Bont

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
NTR1023

# Study information

### Scientific Title
Effect of palivizumab on respiratory syncytial virus-associated burden of disease: a randomised controlled trial [Effect van palivizumab op lange termijn gevolgen veroorzaakt door het respiratoir syncytieel virus: een gerandomiseerde placebo-gecontroleerd onderzoek]

### Acronym
MAKI

### Study objectives
It is not known whether recurrent wheeze in preterm children is caused by respiratory syncytial virus (RSV) infection (serial hypothesis) or that RSV infection is the first indication of chronic airway morbidity that would develop anyway (parallel hypothesis). This study aims to distinguish between these two hypotheses by investigating whether prevention of RSV (by palivizumab) results in decreased incidence of recurrent wheeze.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Medisch Ethische Toetsingscommissie (METC) of the Universitair Medisch Centrum Utrecht, 21 /07/2008

## Study design
Double-blind randomised placebo-controlled multicentre trial with single-blind follow-up study 6 years hereafter

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Respiratory syncytial virus bronchiolitis and post-bronchiolitis wheezing

## Interventions
Infants will receive one-monthly intramuscular palivizumab 15 mg/kg or placebo from discharge until the end of the RSV season with a maximum of five injections.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Palivizumab

## Primary outcome measure
Number of wheezing days during the first year of life

## Secondary outcome measures
1. Questionnaire-reported wheezing, health-related quality of life and health-economic consequences of RSV at age 1, 3 and 6 years

2. Nasopharyngeal swabs for viral analysis during the RSV season in case of a runny nose or mild cough. These samples will be tested for viruses, to determine if the child is infected with RSV and /or other viruses. It is emphasised that RSV infection is not part of the endpoint of this study.

Added 27/06/2014:
3. Lung function at age 6 years
4. Questionnaire-reported asthma-related respiratory symptoms (ISAAC questionnaire) at age 6 years

Updated 07/03/2017:
3. Lung function measured by spirometry at age 6 years with FEV0.5 as primary endpoint
4. Asthma-related respiratory symptoms measured by ISAAC questionnaire at age 6 years with current asthma as primary endpoint. Current asthma is defined as wheeze in the past 12 months and/or use of asthma medication in the past 12 months

### Overall study start date
01/08/2008

### Completion date
01/04/2017

## Eligibility

### Key inclusion criteria
1. Healthy preterm infants
2. Gestational age between 32 and 35 weeks, either sex
3. Children of parents who master the Dutch language

### Participant type(s)
Healthy volunteer

### Age group
Child

### Sex
Both

### Target number of participants
452

### Total final enrolment
429

### Key exclusion criteria
1. A known cardiac anomaly, Down's syndrome or other serious congenital disorders
2. Require intensive respiratory treatment, defined as surfactant treatment or at least 2 weeks of mechanical ventilation
3. Greater than 6 months of age at the start of the RSV season, defined as 1st October of the year of birth
4. Airway morbidity before the start of the RSV season, monitored before the first injection

**Date of first enrolment**
01/08/2008

**Date of final enrolment**
01/04/2017

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Lundlaan 6**
Utrecht
Netherlands
3584 EA

# Sponsor information

**Organisation**
University Medical Centre Utrecht (UMCU) (Netherlands)

**Sponsor details**
c/o Prof. dr. E.A.M Sanders
Lundlaan 6
Utrecht
Netherlands
3584 EA

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.umcutrecht.nl

**ROR**
https://ror.org/04pp8hn57

# Funder(s)

**Funder type**
Industry

### Funder Name
Abbott International plc (UK) - no restrictions for publication of the research data

# 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 | 09/05/2013 | | Yes | No |
| Results article | results | 01/04/2018 | | Yes | No |
| Results article | results | 01/10/2020 | 24/03/2020 | Yes | No |