LONG LOVE: Naar levenslang gezondere LONGen: een multidisciplinair zorgpad voor te vroeg geboren kinderen

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26155

Source
NTR

Brief title
LONG LOVE

Health condition

Prematurity, Wheezing, Respiratory Tract Infections

Sponsors and support

Primary sponsor: Franciscus Gasthuis
Source(s) of monetary or material Support: BeterKeten

Intervention

Outcome measures

Primary outcome

Total number of physician diagnosed lower RTI and wheezing episodes in the first 18 months of life.

Secondary outcome

• time to first lower RTI or wheezing episode
• total number of RTI
• total number of wheezing episodes
• distribution of viruses (in case of hospital admission)
• medication use (bronchodilators, corticosteroids, antibiotics)
• lung function as measured by expiratory variability index
• comparison of expiratory variability index in moderate/late prematurity compared to term cohort
• correlation between expiratory variability index and other pulmonary function analyses
• association between expiratory variability index and number of RTI/wheezing
• outdoor air quality
• indoor air quality
• association between air quality and number of RTI
• quality of life
• classification of high risk patients
• costs- and cost-effectiveness

Study description

Background summary

Rationale: Approximately 8% of all births occur between 30-36 weeks of pregnancy (‘moderate-late’ prematurity) and is associated with the development of chronic obstructive lung disease later in life. Respiratory tract infections (RTI) and wheezing illnesses disproportionally affect preterms in early life resulting in frequent hospitalisation. Besides prematurity, several other modifiable influencing factors are associated with impaired pulmonary development: respiratory tract infections (RTI), local air pollution, tobacco smoke exposition, vitamin D deficiency, maternal stress and antibiotic usage.
Objectives: To identify and treat modifiable influencing factors negatively affecting pulmonary health in moderate-late preterms during the first 18 months of life using an innovative multidisciplinary follow-up framework.

Study objective

We envision that a standardized follow-up framework designed to better monitor pulmonary health in moderate-late preterm infants will reduce respiratory disease and related healthcare consumption. The identification and preventive treatment of modifiable influencing factors and early detection of abnormal pulmonary function in a unique follow-up framework will substantially improve pulmonary health and prevent suboptimal pulmonary development.

Study design

T 3,6,12 and 18 months

Intervention

LONG LOVE Framework

Contacts

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Eligibility criteria

Inclusion criteria

• Gestational age at delivery between 30+0 and 35+6 weeks
• Written informed consent by both parents or formal caregivers

Exclusion criteria

• Underlying other severe respiratory disease such as broncho-pulmonary dysplasia (unexpected in this group) ; diaphragmatic hernia; other serious congenital lung disorders; hemodynamic significant cardiac disease; immunodeficiency; severe failure to thrive; birth asphyxia with predicted poor neurological outcome; syndromic or serious congenital disorders.
• Parents unable to speak and read the Dutch or English language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	19-08-2021
Enrollment:	330
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9688
Other	METC MEC-U : XXXXXXXXXXXX

Study results