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Bacterial mucosal immunotherapy for prevention of lower respiratory tract infections in preterm born infants: follow up studies

Submission date
05/11/2026

Recruitment status
Recruiting

Registration date
23/11/2026

Overall study status
Ongoing

Last Edited
13/11/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A significant proportion of infants born at ≤29+6 weeks' gestation develop lung disease during the neonatal period and are at risk of lung disease later in childhood and adulthood. Respiratory viral infections after discharge from the neonatal unit can worsen existing lung disease and lead to increased healthcare use, including hospital admissions. The BALLOON trial (https://www.isrctn.com/ISRCTN14019493) is investigating whether treatment with Backtek (MV130) can reduce the risk of unscheduled visits to healthcare professionals for lower respiratory tract infections compared with placebo.

This follow-up study aims to assess whether Backtek has a continuing effect for at least six months after treatment has stopped and whether there are any neurodevelopmental safety issues at two years' corrected age. The study will compare Backtek with placebo to determine its effects on longer-term respiratory outcomes, neurodevelopmental outcomes and growth in preterm-born children.

Who can participate?
Infants born at less than 30 weeks' gestation who were recruited to the main BALLOON clinical trial and whose parents or guardians consented to follow-up. Infants must be expected to survive to 18 months and 2 years' corrected age.

What does the study involve?
Participants will be followed up at 18 months and 2 years' corrected age. Parents or guardians will be asked whether they are willing to be contacted for follow-up assessments.

At 18 months' corrected age, parents or guardians will be asked to complete a respiratory questionnaire collecting information on lower respiratory tract infections, wheezing, hospital admissions, medication use and related respiratory outcomes. Growth information will be collected from the Personal Child Health Record ("Red Book") and routine follow-up assessments conducted by local neonatal units.

At 2 years' corrected age, parents or guardians will be asked to complete respiratory questionnaires and the Parent Report of Children's Abilities-Revised (PARCA-R) neurodevelopmental questionnaire. Growth information will again be collected from the Personal Child Health Record and local neonatal unit follow-up assessments.

For children for whom questionnaire data are unavailable, information on symptoms, development, growth, hospital admissions and medication use will be obtained from hospital or general practitioner records. Information on hospital admissions and outpatient attendances will also be obtained from NHS England records. Neonatal and neurodevelopmental data at 2 years' corrected age will be obtained from the Neonatal Research Database via the National Database Analyses Unit at Imperial College London.

What are the possible benefits and risks of participating?
The protocol states that the study aims to assess longer-term respiratory outcomes, neurodevelopmental outcomes and growth in preterm-born children who participated in the BALLOON trial. Possible benefits and risks of participating are not specified.

Where is the study run from?
Cardiff University, UK

When is the study starting and how long is it expected to run for?
November 2026 to June 2030.

Who is funding the study?
1. The National Institute for Health and Care Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme
2. Inmunotek Pharma Ltd.

Who is the main contact?
Dr Sarah Kotecha, Cardiff University, kotechasj@cardiff.ac.uk

Contact information

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
365334

Protocol number
SPON2053-26 H52

Study information

Scientific Title
Bacterial mucosal immunotherapy for prevention of lower respiratory tract infections in preterm born infants: follow up studies

Acronym
BALLOON Follow Up Study

Study objectives
For the BALLOON-follow up (FU) study, it is hypothesised that:
1. There will be continuing effect of the Bactek for at least six months after treatment has stopped after administration during the first year, and
2. There are no neurodevelopmental safety issues with the active treatment at two years of corrected age

To address these hypotheses, this study assesses the following using questionnaires completed by the parents or clinical data from GP and hospital records:
1. Does Bactek, when compared with placebo, improve the longer-term respiratory outcomes (including lower respiratory tract infections, hospital admissions, respiratory drug usage, etc. during second year of life and wheezing (primary outcome) at 18 months and 2 years of corrected age for preterm-born infants recruited to the main BALLOON trial?
2. Does Bactek, when compared with placebo, affect the long-term neurodevelopmental outcomes of preterm-born children at 2 years of corrected age?
3. Does Bactek, when compared with placebo, improve the growth of preterm-born infants in the second years of life?

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 17/04/2026, East of Scotland Research Ethics Service (EoSRES) (TAyside medical Science Centre Residency Block Level 3 George Pirie Way Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; Not provided; tay.eosres@nhs.scot), ref: 26/ES/0032

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Prevention of lower respiratory tract infections in preterm born infants

Interventions
Participants will be followed up at 18 months and 2 years' corrected age. During the initial consent process, parents/guardians will be asked whether they are willing to be contacted for assessment of respiratory outcomes, growth, hospital admissions, and neurodevelopment at 2 years' corrected age.

18-month corrected age follow-up:
1. Parents/guardians will be asked to complete validated respiratory questionnaires at 18 months' corrected age to collect information on lower respiratory tract infections, wheezing, hospital admissions, medication use, and related respiratory outcomes.
2. Growth data will be collected from the Personal Child Health Record ("Red Book"), completed by Health Visitors, and from routine follow-up assessments conducted by local neonatal units.
3. For infants for whom questionnaire data are unavailable, data will be obtained from local hospitals or general practitioners through clinic letters, including information on symptoms, development, growth, hospital admissions, and medication use. Data from the first two years of life will be collected from clinic letters generated at routine follow-up appointments, generally undertaken at corrected ages of 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months.
4. NHS England will be contacted to obtain information on hospital admissions and outpatient attendances.

2-year corrected age follow-up:
1. Parents/guardians will be asked to complete both respiratory questionnaires and the modified validated Parent Report of Children's Abilities-Revised (PARCA-R) neurodevelopmental questionnaire at 2 years' corrected age.
2. Growth data will be collected from the Personal Child Health Record ("Red Book"), completed by Health Visitors, and from routine follow-up assessments conducted by local neonatal units.
3. For infants for whom questionnaire data are unavailable, data will be obtained from local hospitals or general practitioners through clinic letters, including information on symptoms, development, growth, hospital admissions, and medication use. Data from the first two years of life will be collected from clinic letters generated at routine follow-up appointments, generally undertaken at corrected ages of 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months.

4. NHS England will be contacted to obtain information on hospital admissions and outpatient attendances.
5. Neonatal and neurodevelopmental data at 2 years' corrected age will be obtained from the Neonatal Research Database via the National Database Analyses Unit (NDAU), Imperial College London.

Intervention Type
Biological/Vaccine

Phase
Phase III

Drug/device/biological/vaccine name(s)
Backtek (MV130)

Primary outcome(s)
1. respiratory outcomes measured using validated respiratory questionnaires at 18 months and 2 years corrected age

2. Neurodevelopmental outcomes measured using the modified validated Parent Report of Children's Abilities-Revised (PARCA-R) neurodevelopmental questionnaire at 18 months and 2 years corrected age

Key secondary outcome(s)

Completion date
30/06/2030

Eligibility

Key inclusion criteria
1. Infants born at <30 weeks’ gestation who are recruited to the main BALLOON Clinical Trial (https://www.isrctn.com/ISRCTN14019493) who have consented to follow up
2. Anticipated survival to 18 months and 2 years corrected age

Healthy volunteers allowed
No

Age group
Child

Lower age limit
18 Months

Upper age limit
2 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Not meeting the key inclusion criteria

Date of first enrolment
20/11/2026

Date of final enrolment
31/12/2029

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Park Place
Cardiff
Wales
CF10 3AT

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)

NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Inmunotek Pharma Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available