

# Supplementation of very low birthweight (VLBW) babies with probiotic Bifidobacterium breve strain (BBG): a pilot study of tolerability and feasibility

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<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/09/2016	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0024105932

# Study information

## Scientific Title

Supplementation of very low birthweight (VLBW) babies with probiotic Bifidobacterium breve strain (BBG): a pilot study of tolerability and feasibility

## Study objectives

1. Are the available preparations of live Bifidobacterium breve (BBG) at doses of  $0.5 \times 10^9$  colony forming units twice daily and the placebo (killed BBG), tolerated in the newborn baby less than 1500 g birthweight when started on the second day of life?
2. Is it feasible to administer these products on day two of life in this population?
3. Confirmation that this dose of BBG is adequate to achieve bowel colonisation
4. Is there a difference in stool Immunoglobulin A (IgA) concentration at 14 and 28 days of life in association with BBG supplement?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Neonatal Diseases: Low birth weight

## Interventions

Randomised controlled trial, 20 per group to be fed live or killed BBG.

Group A: Bifidobacterium breve live strain

Group B: Placebo (BBG killed strain)

**Intervention Type**

Supplement

**Primary outcome measure**

Thus is a pilot study of tolerability and feasibility. The main study will investigate whether BBG supplement is associated with reduced infection and antibiotic usage in this population.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2002

**Completion date**

31/12/2003

**Eligibility****Key inclusion criteria**

Preterm babies more than 500 but less than 1500 g birthweight with no life threatening congenital malformations

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

31/12/2003

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Homerton University Hospital NHS Trust**  
London  
United Kingdom  
E9 6SR

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Homerton University Hospital NHS Trust (UK)

## **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