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

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
19/09/2016

Condition category
Neonatal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 x 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