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Microbial invasion during parenteral nutrition in surgical infants receiving glutamine

Submission date	Recruitment status	[_] Prospectively registered
19/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/12/2020	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00647036

Protocol serial number
6739

Study information

Scientific Title
Microbial invasion during parenteral nutrition in surgical infants receiving glutamine

Acronym
MIGS

Study objectives
A prospective single-centre double-blind randomised controlled trial to test the hypothesis that the addition of glutamine to parenteral and enteral feeds leads to a reduction in bacterial invasion in surgical infants requiring parenteral nutrition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 08/H0713/31

Primary study design
Interventional

Study design
Single-centre randomised interventional prevention trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Infection, Generic Health Relevance and Cross Cutting Themes; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
Intervention group:
During the period of partial enteral feeding, in which the parenteral intake of glutamine/placebo is reducing, we will supplement the enteral diet with the balance which is no longer being given parenterally. This glutamine will be given as Adamin-G® (SHS International Ltd, Liverpool, UK).

Control group:
The control group will receive Complete Amino Acid Mix (SHS International Ltd, Liverpool, UK; contains 0.7% glutamine). The control group will receive isonitrogenous Vaminolact® (Fresenius-Kabi, Runcorn, Cheshire, UK; this contains no glutamine).

Parenteral glutamine will be given as a chemically stable dipeptide solution (Dipeptiven®, Fresenius-Kabi, Runcorn, Cheshire, UK; L-alanyl-L-glutamine 200 mg/ml) in a dose of 0.4 g/kg/day glutamine equivalent to 0.6 g/kg/day Dipeptiven®, which ensures that the nitrogen intake of the intervention and control infants is equal and that no more than 35% of the total nitrogen intake will be provided by Dipeptiven®.

Study entry: single randomisation only

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Glutamine

Primary outcome(s)
Positive blood cultures, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding

Key secondary outcome(s)
1. Clinical signs of infection, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
2. Elevated levels of endotoxin, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
3. Intestinal function, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
4. Intestinal permeability, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
5. Level of EndoCAb (endotoxin-core antibodies), measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
6. Monocyte HLA-DR expression, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
7. Plasma lipopolysaccharide, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when enteral feeding
8. Presence of bacterial DNA, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding
9. Serum amino acid profile, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding

Completion date
20/07/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment

60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
21/07/2009

Date of final enrolment
20/07/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Great Ormond Street Hospital for Children (UK)

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Sparks (UK)

Alternative Name(s)
Sparks Charity

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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	01/01/2020	29/12/2020	Yes	No