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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

Contact name
Mr Mark Bishay

Contact details
Institute of Child Health
Paediatric Surgery Unit
30 Guilford Street
London
United Kingdom
WC1N 1EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00647036

Secondary identifying numbers
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

Study design
Single-centre randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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 measure
Positive blood cultures, measured at beginning of trial, 5 days after starting PN, introduction of first enteral feeding, when full enteral feeding

Secondary outcome measures
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

Overall study start date
21/07/2009

Completion date
20/07/2011

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 60

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
England

United Kingdom

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

Sponsor information

Organisation
Great Ormond Street Hospital for Children (UK)

Sponsor details

30 Guilford Street
London
England
United Kingdom
WC1N 1EH

Sponsor type
Hospital/treatment centre

Website
http://www.ich.ucl.ac.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	29/12/2020	Yes	No