

Microbial invasion during parenteral nutrition in surgical infants receiving glutamine

Submission date 19/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/12/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

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

Study design

Single-centre randomised interventional prevention trial

Primary study design

Interventional

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

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