

# Microbial invasion during parenteral nutrition in surgical infants receiving glutamine

**Submission date**  
19/05/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
19/05/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
29/12/2020

**Condition category**  
Infections and Infestations

☐ 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

**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?
<a href="#">Results article</a>	results	01/01/2020	29/12/2020	Yes	No