

# The effect on clinical outcome of glutamine supplementation of parenteral nutrition in the surgical newborn infant

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>30/04/2003   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/04/2003 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>09/10/2014       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.ich.ucl.ac.uk/ich/html/academicunits/surgery/sign2/signindex.html>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SP3763

## Study information

Scientific Title

Acronym

SIGN (Surgical Infants Glutamine Nutrition)

Study objectives

We will test the hypothesis that glutamine supplementation in the parenteral nutrition (PN) of surgical infants determines more rapid recovery of intestinal function and reduction in infection rate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from local medical ethics committee (ref: 2/4/002).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Surgical newborn infants on parenteral nutrition

Interventions

The treatment group will receive glutamine-supplemented parenteral nutrition.  
The control group will receive isonitrogenous parenteral nutrition.

All patients will have data collected once a week on clinical state, feeding, liver and renal function tests, ammonia, septic episodes and parenteral nutrition lines

**Intervention Type**

Supplement

**Phase**

Not Applicable

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

Glutamine supplementation

**Primary outcome measure**

1. Infection: episodes of sepsis and septicaemia, timing of sepsis and septicaemia
2. Intestinal function: time to full enteral feeding and time on (days)

**Secondary outcome measures**

1. Growth
2. Nutrient intake
3. Biochemical measures of hepatic function

**Overall study start date**

01/04/2002

**Completion date**

30/09/2004

**Eligibility****Key inclusion criteria**

1. Surgical infants below the age of 3 months, either sex
2. Require parenteral nutrition
3. Have received less than 5 days of parenteral nutrition already

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

250

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/04/2002

**Date of final enrolment**

30/09/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Paediatric Surgery Unit**

London

United Kingdom

WC1N 1EH

## **Sponsor information**

**Organisation**

Action Medical Research (UK)

**Sponsor details**

Vincent House

Horsham West Sussex

United Kingdom

RH12 2DP

**Sponsor type**

Charity

**Website**

<http://www.action.org.uk/>

**ROR**

<https://ror.org/01wcqa315>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Action Medical Research (UK)

**Alternative Name(s)**

actionmedres, action medical research for children, AMR

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**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 | 01/07/2012   |            | Yes            | No              |