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

Submission date 30/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/04/2003	**Overall study status** Completed	
Last Edited 09/10/2014	**Condition category** Surgery	

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

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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?
Results article	results	01/07/2012		Yes	No