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Perioperative glutamine administration: a potential therapy for preventing post-operative immune hypo-responsiveness

Submission date 27/04/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/06/2005	**Overall study status** Completed	
Last Edited 25/05/2016	**Condition category** Surgery	

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

Secondary identifying numbers
04 SG 25

Study information

Scientific Title
Perioperative glutamine administration: a potential therapy for preventing post-operative immune hypo-responsiveness

Study objectives
Intravenous administration of glutamine before, during and after major operations counteracts the immune hypo-responsiveness that follows major surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Post-operative immune hypoparesis in children undergoing major surgery

Interventions
Perioperative intravenous glutamine infusion versus isonitrogenous infusion

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure

HLA DR expression by monocytes, and exvivo production of tumour necrosis factor (TNF) alpha following lipopolysaccharide stimulation

Secondary outcome measures
Since glutamine has been shown to influence phagocytic activity we will measure postoperative changes in ß2 integrin expression and activation, internalization and killing of bacteria and respiratory burst, and circulating pro- and anti-inflammatory cytokines. The endocrine/metabolic response to surgery will be assessed by measuring plasma insulin, cortisol, catecholamines, glucose, lactate and free-radical production (malondialdehyde, nitrate/nitrite). In addition the following clinical variables will be recorded: operative complications (e.g. bleeding, intestinal perforation); early postoperative complications (e.g. wound infection, abscess formation, leakage of intestinal anastomosis, evidence of systemic inflammatory response syndrome [SIRS], positive blood culture, bronchopneumonia, urinary tract infection); duration of mechanical ventilation; length of stay in intensive care unit; duration of inotropic requirement; time to full enteral feeding and duration of hospital stay.

Overall study start date
01/08/2005

Completion date
31/08/2007

Eligibility

Key inclusion criteria
96 Children undergoing major surgery at Great Ormond Street Hospital, London. Patients included will be minimised into the following groups of operations
thoracotomy for oesophageal or lung surgery: Nissen fundoplication; laparotomy for intestinal obstruction; colectomy

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
96

Key exclusion criteria
Patients with pre-existing infection, multi-organ dysfunction syndrome, congenital immune deficiency and congenital or acquired severe liver dysfunction (Child's C) will be excluded.

Date of first enrolment
01/08/2005

Date of final enrolment

31/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surgery Unit
London
United Kingdom
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Sponsor information

Organisation
The Institute of Child Health (UK)

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Sponsor type
Research organisation

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Sports Aiding Medical Research for Kids (SPARKS) (UK)

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