

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

Submission date 27/04/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/05/2016	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 $\beta 2$ 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

WC1N 3EH

Sponsor information

Organisation

The Institute of Child Health (UK)

Sponsor details

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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