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Randomised prospective multicentre trial on the effect of early enteral nutrition on gut barrier permeability in severe acute pancreatitis

Submission date 10/12/2004	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 01/03/2005	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 23/04/2015	**Condition category** Digestive System	[_] Individual participant data [_] 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

Protocol serial number
PANC/EN/2005/v1

Study information

Scientific Title
Randomised prospective multicentre trial on the effect of early enteral nutrition on gut barrier permeability in severe acute pancreatitis

Acronym
PANCREAS 2000 ENSAP

Study objectives
Null hypothesis: Early enteral nutrition in patients suffering from severe acute pancreatitis does not ameliorate the increased gut permeability associated with disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe acute pancreatitis

Interventions
Group one: Enteral nutrition via nasogastric/nasojejunal tube, or sip feed, composition as stratified for each centre. To start immediately after randomisation.

Group two: 'Standard' fluid replacement, oral or via intravenous line, composition as stratified for each centre.

Updated 23/04/2015: the trial did not start due to lack of funding.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Reduction of proportion of patients with increased gut permeatbility from 80% by half to 40%.

Key secondary outcome(s)
1. Reduction in persistent organ failure (3 days) from 35% to 15%
2. Complications (with specific emphasis on infective complications).
3. Length of hospital/ICU stay

4. Return of normal GI function
5. Markers of intestinal ischaemia (Intestinal fatty acid binding protein) and other markers of gut permeability (endocAb), immune/inflammatory response

Completion date
30/04/2007

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Patients aged 18 or over with a proven diagnosis of acute pancreatitis (pain and raised enzymes or computed tomography [CT] evidence) together with systemic inflammatory response syndrome (SIRS) or organ failure (Marshall score 2 or more for any organ system except liver, or Atlanta criteria) present for 24 hours or more, and within 72 hours of onset of symptoms.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2005

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Mary's School Of Medicine & Dentistry at Barts & The London
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
Barts and the London NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration