

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/03/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/04/2015	Condition category Digestive System	<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

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Reduction of proportion of patients with increased gut permeability from 80% by half to 40%.

Secondary outcome measures

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

Overall study start date

01/05/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

66

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

England

United Kingdom

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)

Sponsor details

The Royal London Hospital

Whitechapel Road

London

England

United Kingdom

E1 1BB

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00b31g692>

Funder(s)

Funder type

Government

Funder Name

Barts and the London NHS Trust (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