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The effect of modulating gut microflora on clinical outcome in elective surgical patients.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 27/08/2008	**Condition category** Signs and Symptoms	

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
N0285150582

Study information

Scientific Title

Study objectives
The aim of this study is to investigate whether or not modulation of gastrointestinal microflora might impact upon septic morbidity in surgical patients?

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Sepsis

Interventions
Patients will be recruited from the elective colorectal admissions at Scarborough Hospital and will be randomised by a series of sealed envelopes into one of the four groups when they are seen in the pre-assessment clinic.

Group 1 - Control group.
Group 2 - Will receive Neomycin prior to surgery plus bowel preparation.
Group 3 - Neomycin, bowel prep, plus synbiotics. Group 4 - Neomycin, symbiotics but no bowel preparation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Gut microflora:
1. Nasogastric aspirate
2. Fecal samples.

Gut barrier function:
1. Bacterial Translocation
2. Intestinal Permeability.

Inflammatory response:
1. C reactive protein (CRP)
2. Interleukin-6 (IL-6)
3. AntiEndotoxin core antibody (IgM Endo CAB).

Septic morbidity:
1. Wound infection
2. Intra-abdominal abscess
3. Chest Infection
4. UTI.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/07/2004

Completion date
01/10/2005

Eligibility

Key inclusion criteria
Using bacterial translocation as the primary end point for sample size calculation, if the sample size in each of the 4 groups is 20, alpha=0.05 (2-tailed) a chi-square test will have 80% power to detect a difference in proportions.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria

Failure to obtain informed consent, patients with co-existing infections, patients on antibiotics in the previous 2 weeks before recruitment and patients with severe hepatic or renal failure.

Date of first enrolment
19/07/2004

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of General Surgery
Scarborough
United Kingdom
YO12 6QL

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Yorkshire Alliance R&D Unit (UK)

Funder Name
Scarborough & NE Yorkshire Healthcare 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2007		Yes	No