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Efficacy of probiotics and selective decontamination of the digestive tract in reducing bacterial translocation in patients with pylorus preserving pancreaticoduodenectomy

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
28/01/2009

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR280

Study information

Scientific Title

Acronym
SDD-PRO-Whipple Study

Study objectives
Peri-operative administration of probiotics or selective decontamination of the digestive tract (SDD) has an effect on small bowel bacterial overgrowth and bacterial translocation to lymph nodes in patients undergoing pylorus preserving pancreaticoduodenectomy (PPPD) by protecting or enhancing bowel (mucosa) permeability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local ethics committee

Study design
Multicentre randomised single-blind active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Bacterial translocation in pancreaticoduodenectomy

Interventions
After informed consent, patients will be randomly assigned to three groups:
Group A (n = 10): probiotics
Group B (n = 10): selective decontamination of the digestive tract (SDD)
Group C (n = 10): standard treatment

All patients will receive standardised anaesthesia and post-operative analgesia. The effect of pre-operative prophylaxis regimes can be assessed by bacterial counts in a small jejunal biopsy and an adjacent lymph nodes. Also the effect of the prophylactic regimes on gut permeability, cytokine production and faecal flora will be assessed.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Intestinal permeability and bacterial translocation following major pancreaticobiliary surgery.

Secondary outcome measures
1. Effect of probiotics compared to control treatment on intestinal permeability after major pancreaticobiliary surgery
2. Effect of probiotics compared to control treatment on bacterial translocation to bowel wall and mesenteric lymph nodes
3. Comparison of probiotics to SDD on parameters of intestinal permeability and bacterial translocation
4. Determination of intestinal bacterial overgrowth after probiotics or SDD peri-operative treatment versus control treatment
5. Determination of systemic and local inflammatory response due to bacterial translocation after probiotics or SDD

Overall study start date
01/04/2005

Completion date
01/02/2006

Eligibility

Key inclusion criteria
1. Aged greater than 18 years, either sex
2. Patients planned for pylorus preserving pancreaticoduodenectomy for suspected malignant or premalignant disease
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Antibiotics within a week prior to surgery (peri-operative antibiotics are allowed)
2. Use of other probiotic products 4 weeks before or during the study
3. Non-resectable cancer of the pancreas

Date of first enrolment
01/04/2005

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Winclove BioIndustries BV (Netherlands)

Sponsor details
Papaverweg 36-B
P.O. Box 37239
Amsterdam
Netherlands
1030 AE

Sponsor type
Industry

Website
http://www.winclove.nl/

ROR
https://ror.org/02c0pn910

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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