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

Submission date	Recruitment status	Prospectively registered
20/12/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	Results
Last Edited	Condition category	[] Individual participant data
28/01/2009	Surgery	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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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 preoperative 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