Confidential

PEANUTS 2

Case Report Form

"The use of perioperative antibiotic prophylaxis in the treatment of acute cholecystitis"

Protocol number:

Patient identification number: |__|__|__|

Fictive Initials: |__|__|__|

Center: |_____|

St. Antonius Hospital Nieuwegein
C.S. Loozen, S.C. Donkervoort, A.A.W van Geloven, B. Vlaminckx, J.C. Kelder, C.A.J. Knibbe, H.C. van Santvoort, M.G.H .Besselink, D. Boerma

Gelieve deze formulieren invullen, inscannen en terugsturen naar:
c.loozen@antoniusziekenhuis.nl
Eventueel ook mogelijk om de formulieren per post te sturen naar:
St. Antonius Ziekenhuis, t.a.v. C.S. Loozen/D. Boerma, afdeling heelkunde.
Postbus 2500; 3430 EM Nieuwegein. Fax: 030 603 6578.

Instructions for CRF completion

- The CRF exists of the following parts:
    - *Baseline included in ALEA*
    - *Intake*
    - *Cholecystectomy*
    - *Postoperative hospital stay*
    - *Follow-up 4 weeks postoperative*
    - *Adverse events*
    - *End of study*

- After completing this CRF, it should be signed by the principle investigator to declare the data recorded in the CRF are complete and accurate.

PEANUTS 2

Patient identification number: |__|__|__| **Fictive Initials:** |__|__|__|

Intake

Patient details

Center/hospital	……
Date of randomisation	- - / - - / 20 - -
Initials patient	|__|__|__|
Sex	O Male O Female
Day of birth	- - / - - / - - - -

Clinical and laboratory data

Temperature	|__|__|,|__|
CRP	|__|__|__|
WBC	|__|__|,|__|
Duration of complaints (days)	|__|__|

PEANUTS 2

Patient identification number: |__|__|__| **Fictive Initials:** |__|__|__|

Cholecystectomy

Surgery date:	- - / - - / 20 - -
Conversion	O Yes, indication ……..... O No
Bile culture	O Yes O No
Empyema	O Yes O No
Bile spill	O Yes O No
Severity of cholecystitis (Please encircle what is applicable)	1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10
Comments	……

PEANUTS 2

Patient identification number: |__|__|__| **Fictive Initials:** |__|__|__|

Post-operative hospital stay, at the day of discharge

Clinical data

Length of hospital stay (days) |__|__|

Infectious complication
O Yes, please specify:
- O Superficial wound
- O Deep wound
- O Intra-abdominal
- O Pneumonia
- O Urinary tract
- O Other, please specify …… ……

O No

How is the infectious complication objectified? …….

…….

How is the infectious complication treated? (if treated with antibiotics, please specify type and dose) …….

…….

PEANUTS 2

Patient identification number: |__|__|__| **Fictive Initials:** |__|__|__|

Follow up 30 days postoperative

Outcome

Infectious complication
O Yes, please specify:
- O Superficial wound infection
- O Deep wound infection
- O Intra-abdominal abscess
- O Pneumonia
- O Urinary tract
- O Other, please specify……...

O No

How is the infectious complication objectified? …..……..
……

Other complication
O Yes, please specify ……..
……
O No

Did the patient visit the general practitioner or another hospitals since discharge?

O Yes, please specify ……..
……
O No

Did the patient receive antibiotic treatment since discharge?

O Yes, please specify (type, dose and indication) ……..
……...
O No

Other treatment of complication
O Yes, please specify……...
……
O No

Adverse events

Did any adverse event occur?
O Yes, please fill in the form on the next page
O No

Adverse events

Adverse event (if applicable)

Specify …….....

Start date - - / - - / 20 - -

Stop date - - / - - / 20 - -

Related to the intervention of this study (the absence of antibiotic prophylaxis)?

O Not related
O doubtful
O Possible
O Probable
O Very likely

Severity
O Mild
O Moderate
O Severe

Action
O No action
O Drug administered, specify……
O Other, specify…….....
O Not applicable

Outcome
O Recovered/ resolved
O Not recovered/ resolved
If stabilized, date of stabilization: - - / - - / 20 - -
O Recovered/ resolved with sequelae
O Fatal
If fatal, date of death: - - / - - / 20 - -
O Unknown

Serious adverse event (if applicable)

Serious adverse event?* O Yes
O No

Reason the event is serious?
O Resulting in death
O Life threatening
O Hospitalization/prolonged hospitalization
O Persistent disability/incapacity
O Congenital anomaly/birth defect
O Other medically important serious event

* The principle investigator immediately reports a serious adverse event at ‘toetsing online’

PEANUTS 2

Patient identification number: |__|__|__| **Fictive Initials:** |__|__|__|

End of study

Did the subject completed the entire course of the trial as specified in the protocol?

O Completed
O Discontinued

If discontinued or the subject was not eligible for the trial, specify **the most important** reason for early termination (check one box only)

O Subject violates one or more of the inclusion/exclusion criteria

O Adverse event, please specify……..

O Subject died

Date of death *- - / - - / 20 - -*

Primary cause of death…… O Cause unknown

O Subject lost to follow-up

Date of last contact with subject (visit or call) in this trial: - - / - - / 20 - -

O Subject withdrew consent

Date consent withdrawn *- - / - - / 20 - -*

O Subject non-compliant

O Subject ineligible to continue the trial

O Other, please specify……

PEANUTS 2

Patient identification number: |__|__|__| **Fictive Initials:** |__|__|__|

Principal Investigator's Statement

'*I declare that all entries in the Case Report Form, including corrections, were made by a trial staff member identified on the 'Site Signature Sheet' and that I have checked that all the collected data in the Case Report Form corresponds to a truthful, careful and complete transcription of the data mentioned in the source data, which were generated during the study.*'

If for whatever reason, the principal investigator cannot make the above statement, a medical doctor who has signed the 'Site Signature Sheet' may do so and sign instead.

Principal investigator's name: ……

Signature ……

Date - - / - - / 20 - -

Data entry

Date entry (initials) |__|__|

Control data entry (initials) |__|__|