A Phase III double-blind placebo-controlled randomized trial of aspirin on recurrence and survival in colon cancer patients

Case Report Forms Instructions

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ADMINISTRATIVE RESPONSIBILITIES

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Download the most recent version of CRFs from:
www.aspirinagainstcancer.org

GENERAL GUIDELINES

All data completed on the CRFs must comply with the source data of the patient.
All CRFs should be dated and signed by the investigator or her/his authorised staff members.
All included patients need to be entered into the Dutch Surgical Colorectal Audit (www.dsca.nl)

- The CRF must always be completed in English.
- Always use most recent version of CRFs.
- Write neatly and legibly. Record responses in check boxes using "x" or "☐" or ■.
- Use a ballpoint pen with black or blue ink.
- Use abbreviations sparingly and only use abbreviations that are clear and in standard medical use.
- Enter the Center Id (= hospital number allocated by the Datacenter), Subject Id (= patient serial number within the hospital), Month and Year of Birth or Date of Birth in the spaces provided at the top of each CRF page.
- Make reference to the patient using only the above mentioned patient identifiers.
- Record all laboratory values in the units given at the CRF.
- Do not leave blank spaces. Use the following abbreviation for information that is missing.
    - ND = not done.
    - NA = not applicable.
    - UNK = unknown.
- Where a date is required, enter the date of the assessment, not the date the results of the assessment were reported or the date the CRF was completed.
- Record dates in the format dd/mm/yyyy.
- Ensure that the 'other' category is only used for data which does not fit in one of the listed categories and specify.
- Make comments as clear and concise as possible. Do not enter data or comments on the page margins or outside the allocated spaces, but use the 'comment form' in the CRF booklet.
- To correct an error.
    - Draw a single line through the incorrect entry; do not write over, erase or use correction fluid.
    - Enter the correct data nearby.
    - Date and initial the correction.
- The CRF pages must be send to the Datacenter in Leiden.
- The CRFs must be completed and signed by the investigator or one of his/her authorised staff members as soon as the requested information is available. The time between the patient's visit and completion/shipment of CRF pages should be kept to a reasonable minimum. In all cases it remains the responsibility of the investigator to check that original CRFs are sent to the Datacenter in Leiden and to verify that they are completed and filled out correctly.
- To enable peer review, and/or audits from Health Authorities/DCCG, the investigator must agree to keep records, including a file to identity all participating subjects (Patient Name and Subject Id), all original signed Informed Consent Forms, all copied CRFs. To comply with international regulations, the records should be retained by the investigator for 15 years, including assessments like CT-scans.

CRF	Form	Comment
Randomisation Form	F01	Complete within 2 months after randomisation.
Baseline Form	F02	Complete within 2 months after randomisation.
Follow-up Form	F03	To fill in after every visit, complete within 2 months after each visit. Visit 1 6 months after surgery. Visit 2 1 year after surgery. Visit 3 1.5 years after surgery. Visit 4 2.0 years after surgery. Visit 5 2.5 years after surgery. Visit 6 3.0 years after surgery. Visit 7 3.5 years after surgery. Visit 8 4.0 years after surgery. Visit 9 5.0 years after surgery
Recurrence / New Primary Form	F04	To fill in for every separate occurrence of an event (local or regional recurrence, distant metastases or new primary). For new primary: report any new primary cancer. Complete this form within 1-3 months after all treatments have started.
Concomitant Medication Form	F05	To fill in when chronical concomitant medication start/stop/change.
End of Study Treatment Form	F06	Complete this form when the patient has stopped the allocated treatment in case of early discontinuation or completed treatment as per protocol. Complete this form within 1-3 months after stop of ibandronate treatment.
Off Study Form	F07	To fill in when patient/investigator decide to stop the study. Complete this form within 2 months.
Death Form	F20	To record date and cause of death. Complete this form within 2 months after death.
Adverse Event Form	F30	To record adverse events. Complete this form within 1-3 months after the adverse event. Surgical procedures, new primaries, relapses and CIS are **not** AEs.
Serious Adverse Event Form	F40	To record serious adverse events. Report a serious adverse event by fax to the Datacenter in Leiden within 24 hours and by regular mail within 10 days of the initial observation of the event.
Comment Form	F50	To record comments and additional data.

F01 RANDOMISATION FORM

The first number refers to the general item, e.g. 2 = Inclusion Criteria. The second number (bold on the CRF) refers to the number of each question at the beginning of the line. The third and fourth number refers to subquestions. E.g. question 4.3 is: 4. Specific questions – 3. Date of Surgery.

1. GENERAL INFORMATION
1.1 Physician is the person who is responsible for the randomisation of the patient.
1.2 Center is the center where the chemotherapy and surgery will take place.

2. INCLUSION CRITERIA
All answers must be "Yes" otherwise patient is not eligible
2.1 Adenocarcinoma of the colon must be confirmed by a pathologist
2.2 Staging after surgery conform TNM classification

3. EXCLUSION CRITERIA
All answers must be "No" otherwise patient is not eligible
3.2 Which means: ascal, coumarines, or any other anti-coagulans
3.5 High dose means >20mg/day
3.6 Local recurrent disease means recurrence of the local tumor. Distant recurrence means metastasis of e.g. the liver.21
3.8 SCC: Squamous Cell Carcinoma, CIN: Cervical intraepithelial neoplasia

F02 BASELINE FORM

1. GENERAL
1.1 DSCA number: registration number of Dutch Surgical Colorectal Audit
1.2 CEA pre-operatively; not compulsory

2. ADULT COMORBIDITY EVALUATION-27

Categorie	**Eenheid/afkorting**
Venous disease	PE= Pulmonary Embolism
Respiratory system:	1 mmHg = 1.000000142466321... Torr 1 kPa is equal 7.5006168270417 torr
Gastrointestinal system, hepatic:	Eenheid bilirubine is in mg/dl. 1 mg/dL = 17.1 µmol/L h/o: History of
Renal system	1 µmol/L = 0.0113 mg/dL
Endocrine system	AODM: adult-onset diabetes mellitus IDDM: Insulin Dependent Diabetes Mellitus DKA: Diabetic Keto Acidosis
Rheumatologic	CNS: Central Nervous System

3. G8 GERIATRIC ASSESSMENT SCREENING TOOL & SOCIAL STATUS
3.A According to patient of family member
3.2 Community dwelling: home byhim/herself

F03 FOLLOW-UP visit 1,2,3,4,5,6,7 & additional visit

3. Investigations
3.1 CEA: Carcino-embryonaal antigeen in µg/L
3.2 CEA: Carcino-embryonaal antigeen in µg/L
3.3 CT: Computer Tomography

7. Changes Chronical Concomitant Medication
Changes in type of medication as well as dosage

F04 RECURRENCE/NEW PRIMARY FORM

2. Location(s)
2. Options for locations (other also possible):
Locoregional Recurrence: Colon
Distant metastasis: e.g. liver, lung, bone metastasis
New Primary: e.g. rectal cancer, lungcancer, breastcancer etc.

3. Investigations and Results
3.3 Bone scan is the same as bone scintigraphy

F20 *DEATH FORM*

3. In case 'yes' →enter result deblinding

F40 SERIOUS ADVERSE EVENT *FORM*

1. **Reaction Information**
1.11 A sequela is a chronic condition that is a complication of an acute condition that begins during that acute condition

F50 *COMMENT FORM*

Please specify the form type, page number and information like visit or date with each comment.