Leids Universitair Medisch Centrum

Afdeling Heelkunde, Datacenter, K6-R
Postbus 9600, 2300 RC LEIDEN
datacenter@lumc.nl
Tel: 071-5263500 / Fax 071-5266744

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

Aspirin TRIAL

RANDOMISATION FORM

Center Id	Subject Id	Date of Birth
	8	- - 19

1. GENERAL INFORMATION

1.	Physician _____	☐ surgeon ☐ medical oncologist ☐ gastroenterologist
2.	Center _____	

2. INCLUSION CRITERIA

All answers must be "Yes" otherwise patient is not eligible

		Yes	No
1.	Histologically confirmed adenocarcinoma of the colon	☐	☐
2.	TNM stage: pT3-4; N0-2 and M0, or pT1-2 and N1-2 (UICC stage II and III) (in case of >1 tumour: largest tumour is stage II or III)	☐	☐
3.	Age ≥ 45 years	☐	☐
4.	Completed surgical resection (R0) within 12 weeks of randomisation	☐	☐
5.	Written informed consent according to local Ethics Committee requirements	☐	☐

3. EXCLUSION CRITERIA

All answers must be "No" otherwise patient is not eligible

		Yes	No
1.	Rectal cancer (defined as tumor within 15 cm from the anal verge)	☐	☐
2.	Currently taking oral anti-coagulants.	☐	☐
3.	Currently taking (low-dose) aspirin for any reason	☐	☐
4.	History of bleeding disorders or active gastric or duodenal ulcers	☐	☐
5.	Currently taking high dose (≥ 30 mg predniso(lo)ne) systemic glucocorticoids	☐	☐
6.	Patients with (suspected) (non-) polyposis syndrome (FAP/AFAP, MAP, Lynch syndrome)	☐	☐
7.	Patients with >100 polyps of the colon or a known hereditary syndrome of the colon in a first degree family member	☐	☐
8.	Local or distant recurrent disease	☐	☐
9.	Allergy or intolerance for salicylates	☐	☐
10.	History of other malignancies in the last 5 years, except for SSC, BCC or CIN	☐	☐
11.	Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule	☐	☐

Leids Universitair Medisch Centrum

Afdeling Heelkunde, Datacenter, K6-R
Postbus 9600, 2300 RC LEIDEN
datacenter@lumc.nl
Tel: 071-5263500 / Fax 071-5266744

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

Aspirin TRIAL

RANDOMISATION FORM

Center Id	Subject Id	Date of Birth
	8	X X - - - 1 9

4. SPECIFIC QUESTIONS

1.	Date of written informed consent	☐☐-☐☐-20☐☐
2.	Date of surgery	☐☐-☐☐-20☐☐
3.	Adjuvant chemotherapy	☐ no ☐ yes
4.	Stage	☐ stage II ☐ stage III
5.	Gender	☐ male ☐ female

5. RANDOMISATION

1.	Date of randomisation	☐☐-☐☐-20☐☐

Notes: _____

Your local hospital pharmacist will be automatically notified of the randomisation to be able to deliver the study drug.

Signature Datacenter	Name	Date
Signature Investigator	Name	Date