

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



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RANDOMISATION FORM

CRF: F01 (Page 1 of 2), version 2.2, 06/06/2016

	r Id Subject Id Date of Birth									
	8 - 19									
1.	GENERAL INFORMATION									
1.	Physician Surgeon Surg									
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 <u>and</u> 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									
J.	EXCLUSION CRITERIA All answers must be "No" otherwise patient is not eligible									
3.										
3.		Yes	No							
1.		Yes	No							
	All answers must be "No" otherwise patient is not eligible	Yes	No							
1.	All answers must be "No" otherwise patient is not eligible Rectal cancer (defined as tumor within 15 cm from the anal verge)	Yes	No							
1. 2.	All answers must be "No" otherwise patient is not eligible Rectal cancer (defined as tumor within 15 cm from the anal verge) Currently taking oral anti-coagulants.									
1. 2. 3.	All answers must be "No" otherwise patient is not eligible Rectal cancer (defined as tumor within 15 cm from the anal verge) Currently taking oral anti-coagulants. Currently taking (low-dose) aspirin for any reason									
1. 2. 3. 4.	All answers must be "No" otherwise patient is not eligible Rectal cancer (defined as tumor within 15 cm from the anal verge) Currently taking oral anti-coagulants. Currently taking (low-dose) aspirin for any reason History of bleeding disorders or active gastric or duodenal ulcers Currently taking high dose (≥ 30 mg predniso(lo)ne) systemic glucocorticoids Patients with (suspected) (non-) polyposis syndrome (FAP/AFAP, MAP, Lynch									
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1. 2. 3. 4. 5. 6. 7.	All answers must be "No" otherwise patient is not eligible Rectal cancer (defined as tumor within 15 cm from the anal verge) Currently taking oral anti-coagulants. Currently taking (low-dose) aspirin for any reason History of bleeding disorders or active gastric or duodenal ulcers Currently taking high dose (≥ 30 mg predniso(lo)ne) systemic glucocorticoids Patients with (suspected) (non-) polyposis syndrome (FAP/AFAP, MAP, Lynch syndrome) Patients with >100 polyps of the colon or a known hereditary syndrome of the colon in a first degree family member Local or distant recurrent disease									



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Cente	er Id	Subject	ld	Da	Date of Birth				
		8			X				
4.	SPE	ECIFIC	QU	IES	ΓΙΟΝ	NS			
1.	Date o	of writter	n inforr	med c	onsen	nt			
2.	Date o	of surge	y			- 20			
3.	Adjuva	ant chen	nother	ару		□ no □ yes			
4.	Stage	:				stage II stage III			
5.	Gende	er				☐ male ☐ female			
5.	RAI	NDON	IISA	TIO	N				
1.	Date o	of rando	misatio	on		- 20			
Note	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