A Phase III double-blind placebo-controlled Randomized Trial of Aspirin on Recurrence and Survival in Colon Cancer Patients

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This study has been transitioned to CTIS with ID 2022-502324-48-00 check the CTIS register for the current data. To study the effect of 80mg aspirin (given orally once daily for five years) on fiveyear overall survival (OS) for stage II and III...

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON50659

Source
ToetsingOnline

Brief title
ASPIRIN trial

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
bowel cancer, colon cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars,NutsOhra,NutsOhra;Innovatiefonds Zorgverzekeraars;private donatie

Intervention

Keyword: Acetylsalicylic acid, Colon cancer, Survival

Outcome measures

Primary outcome

The primary endpoint of the trial is five year Overall Survival (5-yr OS).

Secondary outcome

-To study the effect of aspirin on 3 year disease free survival (DFS) in

patients with stage II and III colon cancer.

-To study the effect of aspirin on time to treatment failure (TTF).

-To study the effect of aspirin on toxicity, for example the interaction of

aspirin with chemotherapy.

Study description

Background summary

Colon cancer is one of the most common cancer types in developed country's. In Europe, colorectal cancer is the second cause of cancer death. Recent studies show that the use of aspirin after the diagnosis of colon cancer has a significant survival benefit. Chan et al. found a 30% mortality reduction in patients using aspirin (JAMA 2009;302(6):649-58). The studies done so far were all retrospective cohort analysis. A limitation in these studies is confounding by indication.
Therefore, there is a great need for a randomised trial, mainly when there is a chance for micrometastasis (stage II and III colon cancer). This could lead to a new treatment option after surgery without much side effects and with relatively low costs.

Study objective

This study has been transitioned to CTIS with ID 2022-502324-48-00 check the CTIS register

for the current data.

To study the effect of 80mg aspirin (given orally once daily for five years) on fiveyear overall survival (OS) for stage II and III colon cancer patients

Study design

A phase III doubleblind placebo controlled,randomized trial of adjuvant low-dose aspirin in colon cancer patients.
Patients will be stratified according to:
-Stage (II or III)
-Age (<70/>=70 years)

Intervention

Patients will be randomized for aspirin 80 mg po daily for 5 years versus placebo within 12 weeks after curative resection of the tumour. Aspirin 80 mg or placebo will be used every day for the duration of five years. Followup will be regarding the national guidelines (www.oncoline.nl). There will be no different interventions in the scope of this trial.

Study burden and risks

Most important risk in aspirin use is gastro-intestinal bleeding. Given the widespread use of low dose aspirin in cardiovascular risk management, it is unlikely that new toxicities will be identified. When identified, this will be registered. Every patient will be followed up during five years. During every clinical visit, side-effects of aspirin will be monitored.
Impact, burden and risks for the patients in experimental and placebo-arm:
When randomised for aspirin treatment, patient will use one tablet of aspirin daily during five years.The risk for the patient and the possible side effects that can occur are described above. The followup is not different from the regular followup for patients with colon cancer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients 45 years and older
• Patients with histologically confirmed adenocarcinoma of the colon
• Patients must have TNM stage that is one of the following: pT3-4; N0-2 and M0, or pT1-2 and N1-2 (UICC stage II and III) (in case of >1 tumour: more advanced tumour is stage II or III) (TNM version 7)
• Patients who have undergone curative radical resection (R0 resection) within 12 weeks prior to study entry
• Written informed consent according to national and local regulation

Exclusion criteria

• Patients with rectal cancer (defined as tumour within 15 cm from the anal verge)
• Patients currently taking (low-dose) acetylsalicylic acid or other anti-aggregantia for any reason
• Patients currently taking oral anti-coagulants or use of LMWH or use of DOACs
• Patients with a history of bleeding disorders or active gastric or duodenal ulcers
• Patients currently taking high dose systemic glucocorticoids.(>= 30 mg predniso(lo)n or equivalent)
• 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 (father/mother/brother/sister/son/daughter)
• Allergy or intolerance to salicylates
• Patients with local or distant recurrent disease
• Previous malignancies other than CIN, BCC or SCC with a disease free survival less than 5 years
• Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-01-2015
Enrollment:	1588
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aspirin
Generic name:	acetylsalicylic acid
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-06-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-08-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-11-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-02-2015
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-05-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-09-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-09-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	29-09-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-11-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	03-02-2016
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-07-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-06-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-11-2020
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2022-502324-48-00
EudraCT	EUCTR2011-004686-32-NL
CCMO	NL38132.058.14