

Comparison of intervals between colonoscopic examinations in Familial Colorectal Cancer: The Dutch FAMilial ColorecTAl cancer Surveillance study (the FACTS study) Group

Submission date 26/11/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/12/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/03/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Five to ten percent of all cases of colorectal cancer (CRC) are caused by a combination of hereditary and environmental factors; these cases are collectively referred to as 'familial CRC'. Colonoscopic surveillance is recommended for individuals with familial CRC. However, the appropriate screening interval (between colonoscopic examinations) has not yet been determined. The aim of this study was to compare a 3-year with a 6-year screening interval.

Who can participate?

500 adults aged 45-65, with a family history of CRC.

What does the study involve?

Participants will get a colonoscopy at enrollment in the study to determine if they have certain types of polyps (adenomas) that could become cancerous. These will be removed. If participants have 3 or more adenomas, next colonoscopies will be scheduled after 3 and 6 years. If participants have 0, 1 or 2 adenomas, they are randomly assigned to 2 study groups: follow-up colonoscopy in group A will be scheduled after 6 years, while in group B follow-up colonoscopies will be scheduled after 3 and 6 years. Comparisons between the groups A and B will be made for the presence of advanced adenomas (which have a higher potential of becoming cancerous but are not yet cancerous). This will help us define the interval to recommend between 2 colonoscopies.

What are the possible benefits and risks of participating?

The possible benefit for participants is that, if found at colonoscopy, adenomas from the colon are removed before cancer has developed. This study will also show for this type of population with a family history of CRC whether a 6-yearly interval between examinations/colonoscopies is safe (instead of having a colonoscopy every 3 years). Possible risks are complications of colonoscopy. However, these risks of perforation and bleeding are very low. Participants are instructed when to contact the hospital again. Also, when

the procedure was difficult or complicated, participants are kept under observation in hospital after the procedure (and if needed, treated).

Where is the study run from?

The FACTS study has been set up by the Leiden University Medical Center. Colonoscopies are also performed at collaborating national hospitals in the Netherlands.

When is the study starting and how long is it expected to run for?

Recruitment took place in 2002-2007. The study run for 6 years after inclusion of the last participant in 2007 until mid-2013.

Who is funding the study?

Netherlands Organisation for Health Research and Development.

Who is the main contact?

Professor Hans Vasen

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Contact information

Type(s)

Scientific

Contact name

Prof Hans Vasen

Contact details

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2333 AA

Additional identifiers

Protocol serial number

P02.070

Study information

Scientific Title

Randomized comparison of surveillance intervals in Familial Colorectal Cancer:
The Dutch FAMilial ColorecTAl cancer Surveillance study (the FACTS study) Group

Acronym

FACTS

Study objectives

The aim of this randomized trial was to compare a 3-year with a 6-year screening interval. The hypothesis was that a 6-year screening interval is safe.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee of Medical Ethics at the Leiden University Medical Center, 22/08/2002, ref: P02.070

Study design

Multicentre randomized trial

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Colorectal cancer (CRC)

Interventions

Based on the results of the baseline colonoscopy, patients were assigned to different study groups (group A and B). Patients who had 3 or more adenomatous polyps at baseline were excluded and were scheduled for a follow-up colonoscopy at 3 years. Patients with 0, 1 or 2 adenomatous polyps at baseline were randomized into two groups: group A underwent colonoscopy at 6 years, while group B underwent follow-up colonoscopies at 3 and 6 years.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Presence of adenoma with advanced pathology (AAP), defined as an adenoma with either high grade dysplasia, (tubulo)villous architecture or a size ≥ 1 cm in diameter. This is measured at timepoint 6 years in group A, and at timepoints 3 and 6 years in group B. Polyps are removed during colonoscopies at these timepoints and are revised by one pathologist for characteristics of AAP.

Key secondary outcome(s)

Presence of adenomas.

This is measured at timepoint 6 years in group A, and at timepoints 3 and 6 years in group B. Polyps are removed during colonoscopies at these timepoints and are revised by one pathologist for characteristics of adenomas.

Completion date

01/09/2013

Eligibility

Key inclusion criteria

1. Individuals aged between 45 and 65 years,
2. A positive family history for colorectal cancer (CRC), i.e., one first-degree relative (FDR) diagnosed with CRC <50 years, or two FDRs diagnosed with CRC at any age.

Subjects were excluded if they had 3 or more adenomas at baseline colonoscopy, while those with 0-2 adenomas were randomized into two groups: A) colonoscopy at 6 years and B) colonoscopy at 3 and 6 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

528

Key exclusion criteria

1. Additional first or second-degree relatives with CRC
2. A personal history of inflammatory bowel disease
3. Previous colorectal surgery,
4. A first-degree relative with CRC with known microsatellite instability or strong suspicion of Lynch syndrome (e.g., combination of CRC and endometrial cancer).

Date of first enrolment

01/01/2002

Date of final enrolment

30/08/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands

2300 RC

Study participating centre

St. Antonius Hospital

Nieuwegein

Netherlands
3430 EM

Study participating centre
Diaconessenhuis
Leiden
Netherlands
2300 RD

Study participating centre
Martini Hospital
Groningen
Netherlands
9700 RM

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700 RB

Study participating centre
Isala Clinics
Zwolle
Netherlands
8000 GK

Study participating centre
Radboud University Medical Center
Nijmegen
Netherlands
6500 HB

Study participating centre
Amphia Hospital
Breda
Netherlands
4800 RL

Study participating centre
Maxima Medical Center
Eindhoven
Netherlands
5600 PD

Study participating centre
Catharina Hospital
Eindhoven
Netherlands
5602 ZA

Study participating centre
Medical Center Alkmaar
Alkmaar
Netherlands
1800 AM

Study participating centre
Reinier de Graaf Gasthuis
Delft
Netherlands
2600 GA

Study participating centre
Scheper Hospital
Emmen
Netherlands
7800 RA

Sponsor information

Organisation
Leiden University Medical Center

ROR
<https://ror.org/05xvt9f17>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/12/2015	05/03/2019	Yes	No