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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

Registration date
05/12/2014

Overall study status
Completed

Last Edited
05/03/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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

Primary study design
Interventional

Study design
Multicentre randomized trial

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