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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
26/11/2014		☐ Protocol		
Registration date 05/12/2014	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 05/03/2019	Condition category	[] 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 hfavasen@stoet.nl

# **Contact information**

#### Type(s)

Scientific

#### Contact name

Prof Hans Vasen

#### Contact details

Rijnsburgerweg 10 Leiden Netherlands 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Ves