# Are aberrant crypt foci putative precursor lesions of colorectal cancer: a pilot study

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1) to sample ACF in colorectal mucosa of patients without an increased risk of CRC, patients at an increased of recurrent advanced adenoma based on a personal history of adenomas, patients with established CRC and patients with HNPCC and to...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Malignant and unspecified neoplasms gastrointestinal NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON32090

**Source**
ToetsingOnline

**Brief title**
Aberrant Crypt Foci (ACF) and Colorectaal Cancer (CRC)

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

**Synonym**
Large Bowel Cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Aberrant Crypt Foci, Colonscopy, Colorectal Cancer

## Outcome measures

### Primary outcome

the primary endpoint is to determine number and type of ACF in patients without

an increased risk of CRC, patients at an increased of recurrent advanced

adenoma based on a personal history of adenomas, patients with established CRC

and patients with HNPCC.

### Secondary outcome

The secondary endpoint is to study the activation of the Wnt pathway in ACF and

in matched normal mucosa/advanced adenoma/CRC.

# Study description

### Background summary

colorectal cancer (CRC) is the second most often diagnosed cancer in westernized nations. Aberrant crypt foci (ACF) may represent the earliest precursor lesions in CRC development. Although CRC, adenoma and ACF share same genetic and epigenetic alterations, other links remain to be established between features of colonic malignant tumor, their adenomatous precursors, and ACF, before they are acknowledged as the earliest form of colonic transformation.
The adenomatous polyposis coli and β-catenin genes are the two major components of the Wnt signaling pathway that has been shown to play an important role in the formation of certain cancers. The overactivation of the pathway, which results in abnormal accumulation of beta-catenin protein in nuclei, contributes to most CRCs, both sporadic and hereditary.
We propose that the investigation of normal colonic tissue and ACF for target genes of the Wnt signaling in different patient groups, stratified for CRC-risk, may aid in understanding whether a subset of ACF are likely to progress to cancer and whether this has clinical implications.

### Study objective

1) to sample ACF in colorectal mucosa of patients without an increased risk of CRC, patients at an increased of recurrent advanced adenoma based on a personal history of adenomas, patients with established CRC and patients with HNPCC and to determine whether the number of ACF discriminates among different patient groups stratified by CRC-risk. 2) To understand whether aberrations of regulation of *Wnt signaling* could identify ACF that are likely to progress to cancer.

### Study design

ACF will be discriminated in colonic mucosa by endoscopy during high-resolution close-focus chromoendoscopy. Colonic mucosa will be stained during colonoscopy using indigo carmine to accentuate the contours of ACF. During endoscopy, biopsies are taken from ACF, (but also from CRC if present) and from matched normal mucosa, in different groups of patients according to CRC-risk. The obtained biopsies will be processed and Wnt signaling will be studied using confocal microscopy.

### Study burden and risks

The burden associated with participation in this study is minor. The are very small extra risks due to taking extra biopsies.

## 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

We will enroll patients undergoing colonoscopy for the following indications:
- colorectal cancer screening (10)
- colorectal cancer surveillance because of increased risk of recurrent (advanced) adenoma (10)
- colorectal cancer surveilance in established HNPCC patients (10)
- patients with CRC (pre-surgery colonoscopy) (10)

### Exclusion criteria

Patients with known or suspected inflammatory bowel disease.

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-03-2009 |
| Enrollment: | 40 |

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| Type: | Actual |

### Medical products/devices used

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| Registration: | No |

## Ethics review

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| Approved WMO Date: | 17-06-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

## 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 |
|---|---|
| CCMO | NL21528.041.08 |