

# Hereditary non-polyposis colorectal carcinoma (HNPCC) - a prospective randomized trial for the comparison of prophylactic or extended surgery versus oncological resection in colon or rectum carcinoma

<b>Submission date</b> 09/06/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2007	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

70-2993 Oh 1

## **Study information**

**Scientific Title**

**Study objectives**

Not provided at time of registration

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

HNPCC-associated colorectal carcinoma

**Interventions**

Subtotal colectomy vs. oncologic resection (restorative proctocolectomy vs rectum resection /extirpation)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/01/2002

### **Completion date**

31/12/2004

## **Eligibility**

### **Key inclusion criteria**

1. Colorectal carcinoma fulfilling the Amsterdam-criteria for HNPCC or
2. Colorectal carcinoma in patients with known pathogenic mismatch repair gene mutation or
3. Colorectal carcinoma at the age of 50 or less and detection of microsatellite instability in a tumor biopsy and
4. Age between 18 and 65 years
5. Operability for subtotal colectomy/(restorative) proctocolectomy as estimated by the surgeon
6. Exclusion of metastases, local resection of the complete tumor likely to be possible
7. Elective tumorsurgical operation
8. Willingness of the patient to participate in surveillance required by the trial
9. Informed consent

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

### **Target number of participants**

Not provided at time of registration

### **Key exclusion criteria**

Not provided at time of registration

### **Date of first enrolment**

01/01/2002

### **Date of final enrolment**

31/12/2004

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Klinik für Allgemeine und Viszeralchirurgie

Düsseldorf

Germany

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**Sponsor information****Organisation**

Deutsche Krebshilfe e. V. - German Cancer Aid (Germany)

**Sponsor details**

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**Sponsor type**

Charity

**Website**

<http://www.krebshilfe.de/startseite-dkh.html>

**ROR**

<https://ror.org/01wxdd722>

**Funder(s)****Funder type**

Charity

**Funder Name**

Deutsche Krebshilfe e. V. (70-2993 Oh 1)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration