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# 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

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|---|---|---|
| **Submission date**<br>09/06/2004 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>27/09/2004 | **Overall study status**<br>Completed | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>17/12/2007 | **Condition category**<br>Cancer | [ ] Individual participant data<br>[ ] 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

**Protocol serial number**
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

### Study type(s)
Treatment

### 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(s)
Not provided at time of registration

### Key secondary outcome(s))
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Not Specified

### 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
**Klink für Allgemeine und Viszeralchirurgie**
Düsseldorf
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# Sponsor information

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

**ROR**
https://ror.org/01wxdd722

# Funder(s)

**Funder type**
Charity

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

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration