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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

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