

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

Primary study design

Interventional

Study design

Randomised controlled trial

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

Klinik für Allgemeine und Viszeralchirurgie

Düsseldorf

Germany

40225

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