Trial Description

Title

On board! Rehabilitation after colorectal cancer

Trial Acronym

MIRANDA

URL of the trial

https://www.dkfz.de/de/klinepi/Miranda.html

Brief Summary in Lay Language

Cancer and chemotherapy are often accompanied by exhaustion and pronounced tiredness, which cannot be improved by resting. This is known as cancer-related fatigue. One-third of colorectal cancer survivors suffer from fatigue shortly after initial treatment, but sometimes even years after the end of cancer therapy. Despite the heavy burden on the individual colorectal cancer patient, cancer-related fatigue is not adequately addressed in research. So far, only non-pharmacologic approaches have been shown to be effective.
The MIRANDA study is an observational study and serves to establish a study cohort of patients with non-metastatic ("non-scattering") colorectal cancer that is representative of the German rehabilitation setting. The included patient population will be monitored over a maximum period of 10 years.
The main criteria for participation in the study are hospitalization in one of the cooperating rehabilitation clinics for at least three weeks, diagnosis of non-metastatic colorectal cancer, and surgical removal of the tumor within the past twelve months.
The aim of the cohort study is to gain insights into risk, prevention and prognosis factors of cancer related fatigue, quality of life, the ability to work and further health outcomes among CRC patients. The required information from study participants will be obtained by using questionnaires as well as blood, urine, and stool samples.

Brief Summary in Scientific Language

In Germany, there are more than 60,000 new cases of colorectal cancer and more than 25,000 deaths from colorectal cancer per year. Although the prognosis has particularly improved for the early stages of the disease, detriments in the quality of life often persist. The occurrence of cancer-related fatigue is a major cause of reduced quality of life. One-third of colorectal cancer survivors suffer from fatigue shortly after initial treatment, but sometimes even years after the end of cancer therapy. Despite the heavy burden on the individual colorectal cancer patient, cancer-related fatigue is not adequately addressed in research. So far, only non-pharmacologic approaches have been shown to be effective.

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for participation in the study are hospitalization in one of the cooperating rehabilitation clinics for at least three weeks, diagnosis of non-metastatic colorectal cancer, and surgical removal of the tumor within the past twelve months. The aim of the cohort study is to gain insights into risk, prevention and prognosis factors of cancer related fatigue, quality of life, the ability to work and further health outcomes among CRC patients. The required information from study participants will be obtained by using questionnaires as well as blood, urine, and stool samples. Endpoints, such as cancer-related fatigue, symptoms of depression, quality of life, and functional well-being will be assessed using validated questionnaire instruments (FACIT-F-FS, EORTC-FA-12, GDS-15, EORTC-QLQ-C30, and FACIT-F-FWB) and newly developed questionnaire instruments (e.g. for infection frequency and return to work) every 3 months in the first year and then after 3, 5, 7 and 10 years. Fatalities with causes of death are determined by register matching. At the beginning of the study, blood, urine and stool samples are collected to measure biomarkers and perform genetic analyses. A further stool sample is collected in the fourth month of the study to allow a longitudinal analysis of the microbiome.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

The data is not published to an Open Access Platform. After completion of the study, interested scientists can request data use and receive pseudonymized data upon approval of this application by the sponsor.

Organizational Data

- DRKS-ID: **DRKS00020822**
- Date of Registration in DRKS: **2020/02/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-905/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C18 - Malignant neoplasm of colon**
- ICD10: **C19 - Malignant neoplasm of rectosigmoid junction**
- ICD10: **C20 - Malignant neoplasm of rectum**

ICD10: **C20 - Malignant neoplasm of rectum**

- ICD10: **C21 - Malignant neoplasm of anus and anal canal**

Interventions/Observational Groups

- Arm 1: **At the begin of rehabilitation (baseline):**
  • self-administered questionnaires (see primary and secondary endpoints for further details)
  • measurement of height, weight and waist circumference
  • blood sampling: serum (25(OH)D level, creatinine, calcium, phosphate, albumin, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, C-reactive protein, uric acid), whole blood (hemoglobin, HbA1c, white blood cell count, leukocyte subtype counts) and buffy coat from EDTA Plasma (genome)
  • urine sampling (calcium and creatinine)
  • stool sampling (microbiome)
  • pregnancy test for premenopausal women

  Long-term follow-up:
  • self-administered questionnaires at study month 4, 7, 10 and after 1, 3, 5, 7, 10 years (see primary and secondary endpoints for further details)
  • stool sampling in study month 4 (microbiome)

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

• Cancer-related fatigue assessed by using validated questionnaires (FACIT-F and EORTC-QLQ-FA12) in month 4, 7, 10 and after 1, 3, 5, 7, 10 years

Secondary Outcome

• Overall and domain-specific quality of life assessed by using a validated questionnaire tool (EORTC-QLC C30) in month 4, 7, 10 and after 1, 3, 5, 7, 10 years
• Colorectal cancer-specific quality of life assessed by using a validated questionnaire tool (EORTC-QLQ CR29) in month 10

• Distress in cancer assessed by using a validated questionnaire tool (QSC-R10) in month 10
• Functional well-being assessed by using a validated questionnaire tool (FACIT-F-FWB) in month 4, 7, 10 and after 1, 3, 5, 7, 10 years
• Infection frequencies (total, upper respiratory and lower respiratory tract infections) assessed by self-report of study participants in month 4 and after 1, 3, 5, 7, 10 years
• Return to work assessed by self-report of study participants and by using the count of paid working hours in month 4, 7, 10 and after 1, 3, 5, 7, 10 years
• Disease-related early retirement assessed by self-report of study participants after 1 year
• Subjective ability to work assessed by the short version of the Work Ability Index (WAI) in month 10
• Frailty assessed by using a validated questionnaire tool (FRAIL-Scale) after 1, 3, 5, 7, 10 years
• Falls, fractures including (non-)vertebral and hip fractures assessed by self-report of study participants after 1, 3, 5, 7, 10 years
• Depressive symptoms assessed by using a validated questionnaire tool (GDS-15) in month 4, 7, 10 and after 1, 3, 5, 7, 10 years
• Depressive episodes assessed by self-report of study participants after 1, 3, 5, 7 and 10 years
• Anxiety assessed by using a validated questionnaire tool (GAD-7) after 1 year
• Cancer incidence assessed by self-report of study participants after 1, 3, 5, 7 and 10 years
• Cancer mortality (ICD-10 code C00-C97, D00-D09 or D37-48 as leading cause of death) assessed by register matching after 1, 3, 5, 7 and 10 years
• Colorectal-cancer mortality (ICD-10 code C18-C21 as leading cause of death) assessed by register matching after 1, 3, 5, 7 and 10 years
• Cardiovascular disease mortality (ICD-10 code I00-I99 as leading cause of death) assessed by register matching after 1, 3, 5, 7 and 10 years
• All-cause mortality assessed by the count to all deaths after 1, 3, 5, 7 and 10 years
• Incidence of myocardial infarction and coronary heart disease assessed by self-report of study participants after 1, 3, 5, 7 and 10 years
• Incidence of stroke assessed by self-report of study participants after 1, 3, 5, 7 and 10 years
• Incidence of type 2 diabetes mellitus assessed by self-report of study participants after 1, 3, 5, 7 and 10 years
• Incidence of osteoporosis assessed by self-report of study participants after 1, 3, 5, 7 and 10 years
• Microbiome assessed by obtaining a stool sample in month 4

Countries of recruitment

■ DE **Germany**

Locations of Recruitment

- Medical Center **Klinik Niederrhein (Rehabilitationsklinik), Bad-Neuenahr-Ahrweiler**
- Medical Center **Klinik Rosenberg (Rehabilitationsklinik), Bad Driburg**
- Medical Center **Klinik Nahetal (Rehabilitationsklinik), Bad Kreuznach**
- Medical Center **Klinik Prof. Schedel GmbH (Rehabilitationsklinik), Thyrnau-Kellberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/09/09**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Non-metastatic colorectal cancer patients (ICD-10 C18-21) with Union for International Cancer Control (UICC) stage I-III
• Within 12 months after surgical removal of the tumor
• At least 3 weeks of in-patient rehabilitation in a cooperating clinic are planned
• Sufficient knowledge of the German language and mental capability to be able to give written informed consent and comply with the study requirements

Exclusion criteria

• Subjects who do not consent to participate or who are incapable of giving their own consent will be excluded

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.