Exploratory intervention study: the use of a medical nutrition supplement in patients with metastatic colorectal cancer receiving first line of capecitabine-containing (CAP-containing) treatment

Published: 26-07-2017
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Main study objective: to explore the compliance to nutritional test product intake after the first 3 cycles of systemic therapy in patients with metastatic colorectal cancer receiving first line of CAP-containting systemic treatment. Other study...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52994

Source
ToetsingOnline

Brief title
NUTRACT study

Condition

- Other condition

Synonym
Cancer cachexia, cancer related body weight and muscle loss

Health condition

kanker cachexie, ondervoeding bij kanker

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia
Source(s) of monetary or material Support: Subsidie Utrecht Life Science en Provincie Utrecht. De Utrecht Life Science subsidie is een subsidie bedoeld voor de financiering van het specialized nutrition as part of the Utrecht Centre for Food and Nutrition programma

Intervention

Keyword: Colorectal cancer, Medical nutrition

Outcome measures

Primary outcome

Compliance to nutritional test product intake as measured by:

- The eicosapentaenoic acid (EPA) concentration in the phospholipid fraction of

the erythrocyte membrane [% of total fatty acids] after the first 3 cycles of

CAP-containing treatment (measured in both study groups)

- Test product intake as recorded by the patient in a daily diary after the

first 3 cycles of CAP-containing treatment. The actual test product intake

after the first 3 cycles of CAP-containing treatment as compared to the (as per

protocol) recommended intake will be evaluated.

Secondary outcome

- Body weight [kg]

- Body composition from CT scan: skeletal muscle mass; fat mass; muscle density

- Quality of Life and symptoms: European Organization for Research and

Treatment of Cancer quality of life questionnaire (EORTC) QLQ-C30

and EORTC QLQ-CR29

- Performance status (WHO/ECOG)

- Dietary intake by 3-day dietary record

- Blood parameters

- Evaluation of study participation including experienced changes in sensory

aspects and taste perception.

Study description

Background summary

Recent studies show that muscle mass decreases significantly during palliative systemic treatment in patients with metastatic colorectal cancer. Observational studies suggest that low muscle mass is associated with dose-limiting treatment-related toxicity and poor survival in patients with colorectal cancer undergoing systemic treatment. Therefore, it is important to increase or at least maintain muscle mass during chemotherapy. The medical nutrition supplement that will be studied in the current clinical trial, has been developed to improve or maintain muscle mass as well as body weight and through this to benefit other outcomes, such as quality of life. The current study has been developed with the main focus to investigate the compliance to intake of the medical nutrition supplement in patients with metastatic colorectal cancer after the first 3 cycles of first line capecitabine-containing (CAP-containing) treatment.

Study objective

Main study objective: to explore the compliance to nutritional test product intake after the first 3 cycles of systemic therapy in patients with metastatic colorectal cancer receiving first line of CAP-containting systemic treatment.

Other study objectives: to explore the effect of the test product in patients with metastatic colorectal cancer receiving first line of CAP-containing systemic treatment in comparison with a control group receiving standard of care treatment, on tolerance and safety; systemic treatment related parameters; body weight and body composition; quality of life; dietary intake; blood chemistry.

Study design

The study is a randomized controlled open-label parallel-group single-centre

exploratory study in 1 study centre with multiple satellite centres.

Intervention

The test group will be asked to take the medical nutrition supplement twice per day, during the first 3 cycles of CAPOX-B treatment. The control group receives the same medical CAP-containing treatment and standard of care of nutritional support.

Study burden and risks

Patients in the test group will be asked to take the medical nutrition supplement twice daily, during the first 3 cycles of CAP-containing treatment. The control group receives the same medical CAP-containing treatment and standard of care of nutritional support. Patients in the control group will undergo the same assessments throughout the 3 cycles of systemic treatment as patients in the test group. Most of the study assessments are performed during routine hospital visits required for the treatment of the disease. Study specific assessments are: additional blood withdrawal, (only applicable for the test group:) daily recording of test product intake in a diary, and for both study groups: completing one 3 day dietary record, questionnaires to record gastro-intestinal symptoms, questionnaires to assess quality of life. Patients will also get a study evaluation questionnaire at the end of the study. At the end of the study, patients will be contacted once by phone. Patients in the test group who use specific nutritional supplements will be instructed to replace the use of these supplements by the use of the test product. In addition, patients in both study groups are not allowed to use fish oil containing supplements or consume fatty fish > 2x per week and are not allowed to use specific food supplements during the study. Based on earlier studies with a similar product, no specific adverse effects are expected. Adverse events, laboratory safety outcome parameters and the response to chemotherapy treatment will be evaluated by a physician.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Histologically proven colorectal cancer
2. Presence of distant metastases
3. Eligible and scheduled for first line treatment with CAP-containing systemic treatment
4. Performance status (WHO/ECOG) of 0 or 1
5. Age >= 18 years
6. Written informed consent

Exclusion criteria

1. Presence of ileostoma or ileal pouch
2. Malnutrition Univeral Screening Tool (MUST) score of >=2, indicating high risk of malnutrition
3. Body mass index < 20.0 kg/m2
4. No possibility for the patient to start test product intake 3 days before start of the first systemic treatment cycle
5. Known intolerance or allergy to dairy, fish, or other ingredients of the test product
6. Moderate to severe hypercalcemia, i.e. total calcium level >= 12.0 mg/dL
7. Use of fish oil containing supplements or usual consumption of fatty fish > 2x per week, within 3 weeks prior to entry into the study or expected use during the study
8. Known pregnancy or lactation

9. Current alcohol, drug or medication abuse in opinion of the investigator
10. Investigator*s uncertainty about the willingness or ability of the patient to comply with the protocol requirements
11. Participation in any other intervention studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-03-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	22-03-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-05-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-04-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-07-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL60251.041.17