

# Individualized nutritional counselling during chemotherapy for colorectal cancer (COLONUT)

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22047

### Source

Nationaal Trial Register

### Brief title

COLONUT

### Health condition

Advanced or recurrent colorectal cancer, stage IV

## Sponsors and support

**Primary sponsor:** Vu Medical Center Amsterdam

**Source(s) of monetary or material Support:** KWF Alpe D'Huizes

## Intervention

## Outcome measures

### Primary outcome

Change in skeletal muscle area (cm<sup>2</sup>)between individualized nutritional counselling versus

usual nutritional care during 9 weeks of first line chemotherapy for stage IV colorectal cancer

## **Secondary outcome**

- To compare change in total body lean body mass and segmental lean body mass (DEXA) in patients with stage IV colorectal cancer during 9 weeks of first line chemotherapy between individualized nutritional counselling versus usual nutritional care
- To compare change in skeletal muscle area in patients with stage IV colorectal cancer during 20 weeks of first line chemotherapy between individualized nutritional counselling versus usual nutritional care
- Explore treatment toxicity, treatment intensity, treatment outcome, survival, physical functioning, quality of life and handgrip strength of both study arms
- To explore associations of (changes in) muscle area with (changes in) mid-upper arm muscle circumference, whole body fat free mass (BIA) and whole body lean body mass (DEXA)

## **Study description**

### **Background summary**

The purpose is to study the effect of individualized nutritional counselling compared to usual nutritional care on cross-sectional muscle area in patients with stage IV colorectal cancer during first line chemotherapy. Secondary, effect on total lean body mass, treatment intensity, physical functioning, quality of life and survival will be studied. We hypothesize that patients in the intervention arm benefit from individualized nutritional counseling

### **Study objective**

We hypothesize that patients in the intervention arm benefit from individualized nutritional counselling.

### **Study design**

- Date of study inclusion
- During 9 weeks of first line chemotherapy
- During 20 weeks of first line chemotherapy

## Intervention

Patients in the intervention-arm will receive individualized nutritional counselling by a registered dietitian during standard treatment with chemotherapy. The main goals of the nutritional intervention will be to enable every patient to achieve sufficient protein and energy intake with attention for sufficient intake of micronutrients.

## Contacts

### Public

VU University Medical Center, Department of Nutrition and Dietetics,  
P.O. Box 7057  
M.A.E. Bokhorst - de van der Schueren, van  
De Boelelaan 1117  
Amsterdam 1007 MB  
The Netherlands  
NA

### Scientific

VU University Medical Center, Department of Nutrition and Dietetics,  
P.O. Box 7057  
M.A.E. Bokhorst - de van der Schueren, van  
De Boelelaan 1117  
Amsterdam 1007 MB  
The Netherlands  
NA

## Eligibility criteria

### Inclusion criteria

- Age older than 18 years
- Stage IV colorectal cancer
- Scheduled for treatment with first line chemotherapy
- Either CAPOX(-B), FOLFOX(-B) or capecitabine (-B)
- CT scan suitable for evaluating muscle mass at L3 level
- Understanding of the Dutch language

- Able and willing to give written informed consent

## Exclusion criteria

- Chemotherapy in the previous three months
- WHO performance status higher than 3
- Long-term high dose of corticosteroids: longer than three weeks, more than 10 milligram prednisolon or equivalent

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	110
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	25-10-2013

Application type:

First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 44653

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL4086
NTR-old	NTR4223
CCMO	NL45345.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44653

## Study results