Fit4Chemo: feasibility and effectiveness of a multimodal revalidation program in patients with stage 3 colon carcinoma prior and during adjuvant chemotherapy

Published: 29-10-2020
Last updated: 09-04-2024

This pilot study will be performed to determine the feasibility and effectiveness of a multimodal revalidation program prior to and during adjuvant chemotherapy in patients with stage 3 colon carcinoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON54938

Source
ToetsingOnline

Brief title
Fit4Chemo

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
bowel cancer, colon carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Heelkunde

Source(s) of monetary or material Support: Nationaal Fonds tegen Kanker (NFtK)

Intervention

Keyword: Adjuvant chemotherapy, Colon carcinoma, Fit4Chemo, Revalidation

Outcome measures

Primary outcome

Feasibility will be evaluated by:

- safety: occurance of side effects/complications as a result of the intervention

- adherence of the intervention by patients

- fidelity of the intervention by fysiotherapists

- satisfaction of both patients as fysiotherapists

- practicability of the intervention

- implementability of the intervention

Potential effectiveness will be evaluated by

1. Self-reported functional recovery: difference in physical activity between start and end of revalidation program

2. Observed functional recovery: difference between start and end of revalidation program in quality of life, performance status, fatigue, short physical perforamce battery, maximal exertion, muscle strength, anthropometry, fat-free body mass, nutritional status

3. Time between surgical procedure and start of adjuvant chemotherapy

4. Side effects of adjuvant chemotherapy

5. Compliance of adjuvant chemotherapy

Secondary outcome

Not applicable

Study description

Background summary

In the Netherlands, each year 5,000 people are diagnosed with colon carcinoma with lymph node metastases. These so-called stage 3 colon carcinoma patients require adjuvant chemotherapy to improve survival rates. If this adjuvant chemotherapy cannot be started in time or cannot be fully completed, 5-year survival rates decrease from 75% to 39%. Due to the high risk of complications after surgery (approximately 30-60%), postoperative recovery is often delayed. As a result, in only 50% of patients adjuvant chemotherapy is started in time. Moreover, 50% of the patients undergoing adjuvant chemotherapy drop out or receive a dose reduction due to side effects. Research has shown that optimizing the condition by a multimodal program prior to surgery (prehabilitation) increases a patient*s resilience to withstand surgery. As a results, postoperative complication rates decrease and functional recovery enhances. By analogy, it can be suggested that a comparable program after surgery both ensures patients to start chemotherapy in time and ensures patients to better tolerate adjuvant chemotherapy.

Study objective

This pilot study will be performed to determine the feasibility and effectiveness of a multimodal revalidation program prior to and during adjuvant chemotherapy in patients with stage 3 colon carcinoma.

Study design

This pilot study will be conducted in Noordwest Ziekenhuisgroep location Alkmaar. 15-20 patients with stage 3 colon carcioma eligible for treatment with adjuvant chemotherapy will be included. Included patients will undergo a multimodal revalidation program including high intensity interval training prior to and during adjuvant chemotherapy.

Study burden and risks

Patients will undergo a multimodal revalidation program prior to and during

adjuvant chemotherapy. Patients will perform high intensity interval training and resistance training under supervision of a physiotherapist. The content of the training will be adjusted to a patient's condition and can be adjusted throughout the revalidation program. Physiotherapists are trained to anticipate complex problems in patients with cancer. The high intensity of this revalidation program might be considered as a burden for the patients. However, we know from prehabilitation, in which patiens undergo a training program with similar intensity, that increasing their fitness is of such value that patients do not perceive the high intensity as a high load.

Contacts

Public
Selecteer

Geert Grooteplein Zuid 10 10
Nijmegen 6525GA
NL
Scientific
Selecteer

Geert Grooteplein Zuid 10 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients (>18 years) with stage 3 colon carcinoma eligible for treatment

with adjuvant chemotherapy

Exclusion criteria

Patients <18 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-04-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL73776.091.20

Study results

Date completed:	16-03-2022
Actual enrolment:	16