

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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29292

Source

Nationaal Trial Register

Brief title

Fit4Chemo

Health condition

Stage 3 colon carcinoma

Sponsors and support

Primary sponsor: Stichting Nationaal Fonds tegen Kanker (NFtK)

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

Intervention

Outcome measures

Primary outcome

Feasibility and effectiveness

Secondary outcome

N/A

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 result, 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. 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 objective

A multimodal revalidation program after surgery ensures patients to start chemotherapy in time and ensures patients to better tolerate adjuvant chemotherapy.

Study design

Feasibility will be evaluated by:

- safety: occurrence of side effects/complications as a result of the intervention
- adherence of the intervention by patients
- fidelity of the intervention by physiotherapists
- satisfaction of both patients and physiotherapists
- 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 performance 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

Intervention

Multimodal revalidation program including high intensity interval training and resistance training

Contacts

Public

Radboudumc
Dieuwke Strijker

+31628239648

Scientific

Radboudumc
Dieuwke Strijker

+31628239648

Eligibility criteria

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: Interventional
Intervention model: Other
Allocation: Non controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-09-2020
Enrollment: 20
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL8603
Other	CMO Regio Arnhem-Nijmegen : 2020-6554 (dossiernummer)

Study results