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

Gepubliceerd: 08-05-2020 Laatst bijgewerkt: 18-08-2022

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

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29292

**Bron**
Nationaal Trial Register

**Verkorte titel**
Fit4Chemo

**Aandoening**

Stage 3 colon carcinoma

### Ondersteuning

**Primaire sponsor:** Stichting Nationaal Fonds tegen Kanker (NFtK)
**Overige ondersteuning:** Stichting Nationaal Fonds tegen Kanker (NFtK)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

# Toelichting onderzoek

### Achtergrond van het onderzoek

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. 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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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

**Onderzoeksproduct en/of interventie**

Multimodal revalidation program including high intensity interval training and resistance training

# Contactpersonen

## Publiek

Radboudumc
Dieuwke Strijker

+31628239648

## Wetenschappelijk

Radboudumc
Dieuwke Strijker

+31628239648

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients <18 years

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |

**Controle:** N.v.t. / onbekend

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-09-2020 |
| Aantal proefpersonen: | 20 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8603 |
| Ander register | CMO Regio Arnhem-Nijmegen : 2020-6554 (dossiernummer) |

# Resultaten