

# Predicting postoperative outcome in elderly surgical cancer patients.

## Biomarkers and handgrip strength as predictors of postoperative outcome in elderly

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The effects of the inflammatory response to a surgical procedure on postoperative cognitive decline in elderly cancer patients will be investigated. Preoperative inflammation level, muscle strength, nutritional status and general functioning will be...

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving nog niet gestart                            |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON26102

### Bron

NTR

### Verkorte titel

PICNIC BHAPPY

### Aandoening

Older adults, postoperative cognitive decline, functional decline, inflammatory response, onco-geriatric patients, surgery

### Ondersteuning

**Primaire sponsor:** University of Groningen

**Overige ondersteuning:** University of Groningen

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

A change in cognitive functioning at two weeks, three months and one year postoperatively as measured by the Ruff Figural Fluency Test, Trailmaking Test and Rey's verbal learning test in comparison to the preoperative scores.

## Toelichting onderzoek

#### Achtergrond van het onderzoek

Onco-geriatric surgical patients are at an increased risk of postoperative complications. Especially postoperative cognitive impairment has an enormous impact on quality of life and daily functioning in this population.

An inflammatory response to surgery seems to be related to the development of postoperative cognitive decline, delirium and other postoperative complications.

The aim of this study is to investigate the effects of this inflammatory response and identify predictors and possible confounders like preoperative inflammation level, muscle strength, nutritional status and general functioning on this effect.

#### Doel van het onderzoek

The effects of the inflammatory response to a surgical procedure on postoperative cognitive decline in elderly cancer patients will be investigated. Preoperative inflammation level, muscle strength, nutritional status and general functioning will be investigated as possible confounders of postoperative impairment.

#### Onderzoeksopzet

preoperatively, at hospital discharge or two weeks postoperatively and three months and one year postoperatively

#### Onderzoeksproduct en/of interventie

Not applicable

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

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

- surgery is scheduled more than 24 hours after inclusion in the study as we feel this is the time necessary to obtain test results and plan the intraoperative recording of data.
- surgery under general, local or regional anaesthesia.
- written informed consent given according to local regulations.
- Patients can only be included in this trial once.

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

- any physical condition potentially hampering compliance with the study protocol and follow-up schedule, this includes: severe visual impairment, total deafness or the inability to hold a pencil

- personal time constraints unabling patients to comply to the study protocol
- patients unable to comply with the outcome questionnaires (this includes insufficient knowledge of the Dutch language)

## Onderzoeksopzet

### Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel                                            |
| Blinding:        | Open / niet geblindeerd                             |
| Controle:        | N.v.t. / onbekend                                   |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-06-2014               |
| Aantal proefpersonen:   | 672                      |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 17-01-2014       |
| Soort:          | Eerste indiening |

## 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        | NL4441         |
| NTR-old        | NTR4564        |
| Ander register | : METc2014/095 |

## Resultaten

### Samenvatting resultaten

None