

Immunity in Perioperative Practice

Published: 01-02-2023

Last updated: 11-07-2024

To assess the association between the presence of neutrophil subsets (CD16dim/CD62Lbright and CD16bright/CD62Ldim) and physical activity, physical fitness and complications in patients with esophageal or stomach cancer during curative treatment

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON53931

Source

ToetsingOnline

Brief title

IMPACT

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym

cardia and esophagus cancer), upper gastrointestinal cancer (stomach

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: exercise, immune function, neutrophils, upper gastrointestinal cancer

Outcome measures

Primary outcome

- neutrophil subtypes (assessed via immune markers: CD16, CD11b, CD62L, CD10, CD64, CD11b, CD169, CD14, HLA-DR)
- complications
- physical activity
- physical fitness (aerobic capacity, handgrip strength, physical functioning)

Secondary outcome

- total leukocytes and neutrophils count
- risk for malnutrition
- nutritional intake
- sleep
- perceived immune fitness

Study description

Background summary

Patients with esophageal- or stomach cancer in a curative treatment trajectory have to withstand many immunological stresses, while a strong immune system is important for recovery. It is advised to be physically active during and after all stages of cancer treatment in order to better withstand the impact of medical treatment and improve treatment outcomes. However, little is known regarding the effects of physical activity and physical fitness on the immune system during this treatment. A disbalance in neutrophil subsets CD16dim/CD62Lbright and CD16bright/CD62Ldim as well as neutrophil activation (CD11b, CD10 and CD62L expression) have been identified as potential markers for risk of infection in other patient populations. Furthermore, disbalance in the neutrophil subsets was associated with physiological stress induced by physical activity in healthy adults. The potential role of these markers in early identification of infection risk has not yet been investigated in

patients receiving cancer treatment.

Study objective

To assess the association between the presence of neutrophil subsets (CD16dim/CD62Lbright and CD16bright/CD62Ldim) and physical activity, physical fitness and complications in patients with esophageal or stomach cancer during curative treatment

Study design

Observational cohort design

Study burden and risks

Participation in this study involves minimal risk, because most data will be collected in usual care. Extra measurements include an extra withdrawal of 4 ml blood during standard venapuncture, and measurements via a questionnaire at several points in time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

The participant is...

- Assigned to curative treatment for oesophageal cancer, cardia cancer or stomach cancer, including chemoradiotherapy (CROSS) or chemotherapy (FLOT) and surgical resection
- Above 18 years of age
- Able to understand and speak Dutch or English language

Exclusion criteria

no exclusion criteria

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 29-03-2023

Enrollment: 98

Type: Actual

Ethics review

Approved WMO	
Date:	01-02-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	12-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	04-07-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL82429.041.22