At-home Monitoring of patients during Chemoradiation for Oesophageal canceR: the AMCOR trial

Published: 30-06-2023
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To determine the feasibility of at-home monitoring patients with oesophageal cancer during chemoradiotherapy.

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

Summary

ID

NL-OMON53606

Source
ToetsingOnline

Brief title
the AMCOR trial

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
oesophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: AIT (Austrian Institute of Technology),Nova Biomedical,Siemens Healthineers,Siemens Healthineers;AIT en Nova Biomedical

Intervention

Keyword: at-home monitoring, chemoradiation, oesophageal cancer

Outcome measures

Primary outcome

At least 80% of participants complete at least 80% of predefined at home

measurements.

Secondary outcome

n.a.

Study description

Background summary

Chemoradiotherapy is part of standard treatment for patients with locally advanced oesophageal cancer. Some patients with oesophageal cancer treated with chemoradiotherapy do not complete treatment due to toxicity, or face complications after treatment. Therefore, there is a need for better tools for assessing patients' fitness for chemoradiotherapy and to pick up early signals of deteriorating overall physical condition and complications during and after treatment to timely implement supportive care measures. Tools enabling monitoring physical activity, vital parameters and creatinine concentration in the blood at home are available but have not yet been implemented in patients undergoing chemoradiotherapy for oesophageal cancer. The feasibility and added value remain unknown.

Study objective

To determine the feasibility of at-home monitoring patients with oesophageal cancer during chemoradiotherapy.

Study design

Observational study.

Study burden and risks

Participants will collect biometric and quality of life data for ~10 weeks at home. Continuous step counting will be used to register physical activity. Participants will be asked to measure their blood pressure, heart rate, oxygen saturation level, pain level and temperature each morning, and weight 3 times a week. These measurements consume little time and are not harmful. Once a week they will perform a finger stick test themselves to determine creatinine concentration in the blood. This measurement is a small burden to patients as the finger prick can cause pain. There is a small risk of an infection at the finger prick site. In addition, patients fill in three questionnaires at four time points which will take approximately 20 minutes to complete. We do not foresee reasonable risks of these diagnostic procedures for the participants. For the individual participant, a potential benefit may be that relevant changes in physical condition are noticed earlier, potentially resulting in timely implementation of supportive measures. However, it is also possible that patients must make an extra visit to the hospital as a result of abnormal measurements, for example in case of tachycardia.

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

1. Age >= 18 at the time of signing informed consent.
2. Histologically proven adenocarcinoma, squamous cell carcinoma or mixed type of the oesophagus or gastro-oesophageal junction.
3. Indication for definitive or neoadjuvant CRT, with chemotherapy that consists of weekly carboplatin/paclitaxel.
4. Written, informed consent.
5. Ability to comply with all protocol required actions (at home measurements are done individually by the participant him- or herself).

Exclusion criteria

1. Altered mental status, or any psychiatric condition that would prohibit the understanding or rendering of informed consent or the carrying out of the measurements at home.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	30-06-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	01-11-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL83242.042.22
Other	volgt