Patient recorded indexing measurements

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

Summary

ID

NL-OMON54788

Source
ToetsingOnline

Brief title
PRIMs

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer cachexia - emaciation in cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cachexia, cancer, chemotoxicity, phenotype

Outcome measures

Primary outcome

The primary objective of this study is to obtain accurate data regarding physical activity and body weight loss over time in patients with cancer, who are undergoing primary curative cancer therapy (surgery or chemotherapy), and relate this to adverse events of their treatment (postoperative complications and/or chemotoxicity).

Secondary outcome

1) Evaluation of the association between body weight and physical activity in patients with cancer receiving primary curative cancer treatment.

2) evaluation of the association between body weight changes, physical activity and body composition analysis in relation to survival in patients with cancer.

3) Evaluation of the association between body weight changes, physical activity and body composition analysis in relation to radiological or pathological treatment response in patients with cancer

Study description

Background summary

Cancer induced cachexia is a complex condition comprising adipose tissue- and muscle wasting due to several metabolic imbalances. Cachexia has been associated with higher mortality, higher chemotherapy induced toxicity and worse outcome after surgery, thus impacting cancer treatment and outcome vastly. In cancer patients, cachexia is hallmarked by a rise in energy expenditure. Sadly, combatting cancer cachexia-related wasting with nutritional supplementation and dietary counseling has proven to be unsuccessful. Furthermore, due to bias related to inherent subjective self-reporting, currently available data on body weight-loss are inaccurate. Developing a detailed and accurate understanding of patient activity and weight loss are

paramount as they form the basis of the consensus definition of cancer cachexia. Moreover, this understanding will supply a blueprint for the development of an effective treatment algorithm for cancer induced cachexia. By investigating the relationship between these data and adverse events of treatment (postoperative complications and/or chemotoxicity), future research might be able to prevent these problems.

Study objective

The primary objective of this study is to obtain accurate data regarding physical activity and body weight loss over time in patients with cancer who are undergoing primary curative cancer treatment (chemotherapy or surgery) and relate this to adverse events of treatment (postoperative complications and/or chemotoxicity).

Study design

Observational

Study burden and risks

There are some small risks involved in participating in this study. One blood sample will be taken. A venipuncture has a small risk of a small local hematoma. Patients are screened during regular pre-operative consultation of their physician. Screening consists of the Timed Up and GO test, Chair stand test, 2 minute walking test, grip strength analysis, steep ramp test and short nutritional assessment procedure. Screening is done by an experienced physiotherapist to acquire accurate baseline data. Since this procedure is already part of regular treatment and is supervised by an experienced physiotherapist there is no risk nor extra burden associated with these tests. Patients will be monitored for activity and weight in their home situation. A wrist-worn accelerometer, memory integrated weight scale and food diary will be used to acquire data on physical activity and weight. There is no risk associated with this monitoring. There is however a slight burden for patients participating. The wrist-worn accelerometer will be worn 24/7.

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

• Age >= 18
• Diagnosed with cancer
• Planned for primary curative cancer treatment (surgery or chemotherapy)

Exclusion criteria

• ASA-classification V,
• severe liver cirrhosis Child grade C,
• end stage renal disease requiring dialysis,
• severe heart disease New York Heart Association class IV,
• chronic obstructive pulmonary disease (COPD) requiring (home)oxygen therapy,
• Patients must be *mobile*. They may not be bedridden or in a wheelchair.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-09-2019
Enrollment:	322
Type:	Actual

Medical products/devices used

Generic name:	Actigraph wGT3x-BT ;Tanita 601 SD
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-02-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-11-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-12-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-11-2023

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-11-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL65402.068.18