Body composition in renal cell cancer: associations with survival outcomes, tumour characteristics, lifestyle habits, and circulating biomarkers

Published: 02-03-2017
Last updated: 14-04-2024

The primary objective is to get a comprehensive insight in the role of body composition features in RCC, and how these are related to patient-, tumour- and lifestyle-related factors, circulating biomarkers, and recurrence and survival.The research...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON42904

Source
ToetsingOnline

Brief title
ReLife

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
kidney cancer, renal cell cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Biomarkers, Body composition, Lifestyle, Renal cell carcinoma

Outcome measures

Primary outcome

The main study endpoints are cross-sectional area and mean radiodensity of SM, VAT, and APF at baseline.

The main study parameters are patient and tumour characteristics, dietary and physical activity habits, and circulating concentrations of biomarkers (in total 18 parameters, e.g. age, sex, tumour stage, and energy intake).

Secondary outcome

Secondary study endpoints are cross-sectional areas and mean radiodensity of SAT, IMAT, and TAT at baseline, cross-sectional areas and mean radiodensity of all body composition features at follow-up, and changes in cross-sectional areas and mean radiodensity of all body composition features per year.

Secondary study parameters are other patient and tumour characteristics, dietary and physical activity habits, and circulating concentrations of biomarkers.

Study description

Background summary

In the Netherlands, over 2300 men and women are diagnosed with renal cell cancer (RCC) annually.

Excess body weight, expressed as body mass index (BMI) >=25 kg/m2, is an

important risk factor for RCC. More than 60% of RCC patients present with excess body weight and suffer from obesity-related comorbidities. In contrast, excess body weight has been associated with improved recurrence-free, cancer-specific, and overall survival in RCC patients.

However, BMI cannot distinguish between amount and quality of adipose tissue and skeletal muscle (SM), nor between visceral (VAT) and subcutaneous adipose tissue (SAT) and adherent perinephric fat (APF). In patients with other cancer types, recent studies showed that preoperative low SM mass, low SM quality, and high VAT mass were better predictors of prognosis than BMI. And that these were associated with worse overall survival, independent of BMI. Potential mechanisms underlying this association are unfavourable circulating concentrations of VAT-derived pro-inflammatory and pro-tumorigenic adipokines (e.g. adiponectin, leptin). These molecules have been associated with a low-grade systemic inflammation and with worse overall survival in these patients.

We hypothesize that body composition features better predict RCC prognosis than BMI, and are potential targets for tertiary prevention. To date, this has not been adequately studied. In order to develop tertiary prevention trials for RCC patients, we need to get a comprehensive insight in the role of body composition features in RCC, and how these are related to patient-, tumour- and lifestyle-related factors, circulating biomarkers, and recurrence and survival.

Our ultimate aim is to provide RCC patients with personalized advice about weight management to improve their prognosis.

Study objective

The primary objective is to get a comprehensive insight in the role of body composition features in RCC, and how these are related to patient-, tumour- and lifestyle-related factors, circulating biomarkers, and recurrence and survival.
The research questions include:
1. Are patient and tumour characteristics associated with body composition features in RCC?
2. What are the lifestyle habits of RCC patients, and are they associated with body composition features?
3. Are circulating adipokines associated with body composition features in RCC?
4. Are body composition features associated with cancer recurrence and survival in RCC, and is this association independent of BMI?

Study design

To answer the research questions, a prospective cohort study will be conducted. Participants will be asked twice (~4 months and ~10 months after diagnosis):
- to fill in questionnaires (general, diet, physical activity)

- to wear an accelerometer (7 days)
- to donate blood in their own hospital. We will try to organize the blood collection at the same time as the follow-up appointments, so participants do not need to visit the hospital an extra time.
CT scans will be obtained from the treating physicians. Relevant information on clinical data (e.g. tumour characteristics, surgery, therapy) will be obtained from the medical files and the NCR.

To answer research questions 1 and 4, also a historical cohort study will be conducted. For that study, which does not fall under the WMO, another protocol has been written which has been approved by CMO Arnhem-Nijmegen [CMO 2015-1822].

Study burden and risks

This study does not involve any clinical treatment or intervention. The only risks associated with participation in this study are confined to the normal risks of taking blood samples (risk of fainting and of bruising). Since the drawing of blood will be done by professionals, risks are low. The burden for participants includes, at two time points: 1) filling out a general questionnaire and a questionnaire about dietary intake (estimated time required about 1,5-2 hours per time point), 2) wearing an accelerometer for 7 consecutive days, and 3) donating blood samples. This study can therefore be classified as a negligible risk study (negligible risk of harm and negligible severity of harm).

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Noord 21
Nijmegen 6525 EZ
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Noord 21
Nijmegen 6525 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Stage I-III RCC, diagnosed from 2017
- Aged between 18 and 75 years at diagnosis
- Able to communicate in Dutch, to read and understand the patient information and informed consent form
- Able to fill out questionnaires, and to visit the hospital to donate blood samples

Exclusion criteria

Patients diagnosed with another type of cancer in the 5 years before RCC diagnosis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	06-02-2018
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	02-03-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL59329.091.16