Identification of predictive parameters for colitis in melanoma patients treated with immunotherapy.

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To identify predictive parameters for colitis in melanoma patients treated with immunotherapy

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

Summary

ID

NL-OMON41415

Source
ToetsingOnline

Brief title
Biomarkers for immunotherapy-induced colitis

Condition

- Skin neoplasms malignant and unspecified

Synonym
melanoma, skin cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biomarkers, colitis, immunotherapie, melanoma

Outcome measures

Primary outcome

- DNA profile to identify genetic risk factors in 10 mL EDTA.

- Colitis based on clinical symptomatology, sigmoidoscopy, pathological findings from biopsies and immunological tests in those biopsies.

- Defining the severity of epithelial dysfunction measured with MAYO score and BRISTOL stool scale, the measurement of calprotectin level and microbiome composition in the stool and serum IL-8, citrullin, FABP, calprotectin, endotoxin and CRP levels during visits to the outpatient clinic.

Secondary outcome

A simple, cheap, diagnostic test will be developed using these data which can be rapidly adopted in clinical practice (e.g. calprotectin level in the stool or serum IL-8, citrullin, FABP, calprotectin, endotoxin and CRP-levels, or a combination).

Study description

Background summary

Immunotherapy is an interesting treatment option for patients with metastatic melanoma. However, in about 10% of patients treated with immunotherapy a grade 3-4 colitis will occur. We want to find a good predictive biomarker to select patients that are prone to grade 3-4 colitis.

Study objective

To identify predictive parameters for colitis in melanoma patients treated with

immunotherapy

Study design

It will be a pilot study in which melanoma patients treated with immunotherapy will be followed during treatment. It consists of three parts: 1.) to identify a genetic profile associated with immunotherapy-induced colitis, 2.) to identify predictive biomakers for immunotherapy-induced colitis and 3.) to study the tissue of immunotherapy-induced colitis. Patients are able to participate in one, two or all parts of the study.

Study burden and risks

Patients have no direct benefit from participation in this study.
Risks:
- Blood samples will be collected for biomarkers every regular visit, and DNA isolation at baseline.
- Patients collect stool at home and store in in a freezer until it is picked up at home
- During sigmoidoscopy in case of suspect colitis, additional biopsies are optional.
- A daily stool diaty is filled in

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. patients with melanoma who will be treated with immunotherapy
2. signed written informed consent
3. able to comply with the protocol

Exclusion criteria

1. patients with a pre-existing colitis (e.g. Crohn*s disease, ulcerative colitis)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2013
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-12-2017
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	NL39845.042.12