The use of fecal calprotectin in detecting immunotherapy induced colitis and feasibility for the use of immunohistochemical markers in patients receiving checkpoint inhibitors’- a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25248

Source
Nationaal Trial Register

Brief title
COLIT-1

Health condition

colitis

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: NKI-AVL

Intervention

Outcome measures

Primary outcome

Difference in fecal calprotectin levels in relation to severity of endoscopic colitis

Secondary outcome

- Difference in mucosal regulatory foxp3+ T cells and their expression of cytokine profiles between patients with and without colitis

- Endoscopic and histologic findings in patients with colitis in both affected and non-affected mucosa.

- Risk factors for developing immunotherapy induced colitis

- Age and gender of patients;

- Type of malignancy;

- Type and dose of immunotherapy (and combination with other anti-cancer therapy);

- history of auto immune disease;

- baseline fecal calprotectin

- The correlation between complaints, fecal calprotectin levels and endoscopic image

- interval between start checkpoint inhibitors and symptoms

- presence of gastrointestinal symptoms (diarrhea, mucus or blood in stool, abdominal pain)

- complications of colitis (perforation, death)

- other irAEs

Study description

Background summary

Primary: To determine fecal calprotectin levels in patients treated with checkpoint inhibitors.

Study objective

To analyse whether fecal calprotectin is a useful marker in distinguishing colitis from diarrhoea with other causes and whether fecal calprotectin is a useful marker for early detection of colitis.

Study design

study will be completed if 8 patients with colitis will be included in the study

Intervention

Participants are asked to collect feces every two or three weeks (depending on the interval of the administration of the immunotherapy) starting prior to the first cycle of immunotherapy until 2-3 weeks after the last cycle. They will be questioned every 2-3 weeks (either during regular visits or by means of a telephone call) about gastro-intestinal symptoms.

If patients experience gastrointestinal symptoms which may indicate colitis a colonoscopy with at least 10 biopsies will be performed

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years

- Starting with anti CTLA-4 antibodies alone or in combination with anti PD-1 antibodies for a malignancy

- Signed informed consent

Exclusion criteria

There are no exclusion criteria for participation in this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2016
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42995
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5660
NTR-old	NTR5795
CCMO	NL56864.031.16
OMON	NL-OMON42995

Study results