TriaL to investigAte imMune checkpoint inhibitor related siccA syndrome

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56760

Source
ToetsingOnline

Brief title
LAMA trial

Condition

- Other condition
- Ocular sensory symptoms NEC

Synonym
dry eyes and/or dry mouth

Health condition

speekselproductie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: fellowship project

Intervention

Keyword: adverse events, immune checkpoint inhibitors, sicca syndrome

Outcome measures

Primary outcome

The main objective of this study is to examine the incidence and severity of sicca symptoms after ICI administration at 3 and 6 months. Depending on the results of this study, we will consider to perform a future study to evaluate the effect of early administration of low dose steroids to treat symptoms of the sicca syndrome.

Secondary outcome

Secondary objective(s):

The secondary objectives are:

1) to measure changes in objective measures of oral and ocular dryness after ICI administration;

2) to investigate whether IFN signatures are a predictive marker of sicca syndrome.

Exploratory objective

To evaluate the efficacy of early administration of low dose steroids for patients with reported sicca.

Study description

Background summary

Although sicca syndrome is a well-known immune related adverse event (irAE) in patients treated with immune checkpoint inhibitors (ICIs), its incidence and spectrum of severity is largely unknown. Based on daily clinical experience, it is expected that milder sicca symptoms are underreported since patients might not always report these spontaneously.

Study objective

The primary objective is to determine the incidence and severity of sicca complaints after ICI administration. The secondary objectives are: 1) to measure changes in objective measures of oral and ocular dryness after ICI administration; 2) to investigate whether interferon (IFN) signatures are predictive of sicca syndrome. An exploring endpoint is to evaluate the efficacy of early administration of low dose steroids when patients have sicca.

Study design

This is a single institution, prospective study in Erasmus Medical Center to investigate sicca syndrome after treatment with ICI.

Study burden and risks

The ICIs are administered according to standard of care. There are no additional risks due to participation in this trial. We expect that there will be more attention for sicca symptoms which may result in earlier detection. Then, patients may benefit from (early) advice and treatment for (severe) sicca symptoms according to standard care.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Treatment with first-line monotherapy anti-PD(L)1 or combination therapy with anti-PD(L)1 and anti-CTLA4 for the treatment of e.g. melanoma, renal cell, esophagus, and urothelial cell cancer.
• ICI can be administered in the metastatic, inoperable or (neo)adjuvant setting in accordance with the current standard of care.

Exclusion criteria

Exclusion criteria are the following:
• Combination therapy with chemotherapy, targeted therapy or tyrosine kinase inhibitors
• Previous treatment with ICI, including anti-PD(L)1 and anti-CTLA4
• Concurrent treatment with the following medication: anticholinergic medications, alpha receptor antagonist, antipsychotics, and antihistamines
• History of systemic autoimmune disease (rheumatoid arthritis, Sjögren*s disease, systemic sclerosis, inflammatory myopathies and sarcoidosis)
• History of salivary gland irradiation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	08-05-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL86156.078.24