SerUM markers in MERkel Cell Carcinoma patients: a longitudinal moniTorIng study for optiMization of European guidelines.

Published: 30-12-2022
Last updated: 27-12-2024

PRIMARY OBJECTIVETo assess the diagnostic performances (specificity, sensitivity, positive and negative predictive values) of monitoring blood biomarkers (T-Ag antibodies and miR375 levels) for detection of recurrence of disease during follow up....

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

Summary

ID

NL-OMON53695

Source
ToetsingOnline

Brief title
SUMMERTIME

Condition

- Skin neoplasms malignant and unspecified

Synonym
neuroendocrine carcinoma, trabecular carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: University Hospital Center of Tours
Source(s) of monetary or material Support: de sponsor

Intervention

Keyword: Merkel cell carcinoma, Serum markers

Outcome measures

Primary outcome

MCC recurrence (either local, nodal or distant metastases after baseline, assessed by radiological and/or histological assessment) at any time of follow up. Diagnostic performances (specificity, sensitivity, positive and negative predictive values) for disease recurrence will be assessed for each blood biomarker (increase in T-Ag antibodies and miR375 levels).

Secondary outcome

MCC progression after baseline, assessed by radiological assessment (RECIST criteria), at any time of follow up. Diagnostic performances (specificity, sensitivity, positive and negative predictive values) for disease progression will be assessed for each blood biomarker (increase in T-Ag antibodies and miR375 levels). Recurrence-free survival, Overall survival, Disease specific survival according to clinical factors (age, AJCC stage, MCPyV status and immune suppression) and biomarkers at baseline (T-Ag antibodies and miR375 levels) will be determined.

Study description

Background summary

Merkel cell carcinoma (MCC) is a rare aggressive skin carcinoma. Approximately 80% of MCC are related to the Merkel Cell Polyomavirus (MCPyV).
Although rates of relapse are high, the follow-up strategy lacks consensus.
Patients are usually assessed clinically every 3 to 6 months for the first 2-3

years, and every 6 to 12 months thereafter. In the European guidelines, patients with early stages are monitored with clinical examination and ultrasonography of lymph nodes, while wholebody imaging is optional in patients with stage III disease, on a yearly basis for 5 years. Such strategy may prevent the diagnosis of infraclinical recurrences, whereas patients could still be treated with surgery or radiation therapy. Until 2017, patients with advanced disease were treated with chemotherapies, with no long-term benefit. Immunotherapies with PD-1/PD-L1 inhibitors currently allow durable responses in 50% of such patients. This major change in the management of MCC patients argues for a follow-up strategy that would allow early diagnosis of infra-clinical metastases, when tumoral burden is still low. Given that all patients cannot be monitored by systematic regular imaging, additional non-invasive tools are needed. Blood-based biomarkers as a surrogate of tumor burden are advantageous as they can be repeated over time, providing guidance on when imaging is necessary. The study aims to assess two blood biomarkers, MCPyV T-Ag antibodies and cell-free miR-375, in a prospective fashion from baseline diagnosis, in a cohort of 150 European MCC patients

Study objective

PRIMARY OBJECTIVE
To assess the diagnostic performances (specificity, sensitivity, positive and negative predictive values) of monitoring blood biomarkers (T-Ag antibodies and miR375 levels) for detection of recurrence of disease during follow up.

SECONDARY OBJECTIVES
To assess the diagnostic performances (specificity, sensitivity, positive and negative predictive values) of monitoring blood biomarkers (T-Ag antibodies and miR375 levels) for progression of disease during follow up. To assess the diagnostic performances (specificity, sensitivity, positive and negative predictive values) of each blood monitoring strategy (either use of biomarker 1, biomarker 2 or both) for detection of recurrence of disease during follow up. To assess clinical factors and biomarkers at baseline that are associated with outcome (recurrence, response to treatments and death).

Study design

Prospective clinical trial

Study burden and risks

during regular meetings, 5 times 5 ml blood will be collecting in a period of 1 year.

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 a « de novo » diagnosis of MCC, confirmed on histological criteria (neuroendocrine morphology, CK20 staining and/or neuroendocrine and/or SATB2 staining, exclusion of differential diagnosis)
2) >= 18 years of age
3) Written informed consent obtained from the participant

Exclusion criteria

1) Patients following any measures of legal presentation

2) Pregnancy or breastfeeding

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2023
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	30-12-2022
Application type:	First submission
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
ClinicalTrials.gov	NCT04705389
CCMO	NL79978.068.22