Real-world experience with immune checkpoint inhibitors and targeted therapy in patients with metastasized conjunctival melanoma: An Ophthalmic Oncology Group multicenter cohort study

Project leaders: Robert M. Verdijk and Ellen Kapiteijn, Leiden University Medical Center, Albinusdreef 2, Leiden 2333ZA, the Netherlands

Email: R.M.Verdijk@lumc.nl

h.w.kapiteijn@lumc.nl

Background

The introduction of targeted therapies and immune checkpoint inhibitors (ICIs) has improved the survival of patients with advanced melanoma, especially for cutaneous melanoma (CM), in both trial and real-world settings. BRAF and MEK inhibitors are (similar to the situation in cutaneous melanoma) the most well-studied small molecule inhibitors in metastatic conjunctival melanoma (CoM), yet only single cases and small case series have been published. Similar, reports on ICI in metastatic CoM are scarce. With the small numbers and various different treatment regimens, it is currently impossible to make any conclusions on the efficacy on the outcomes of targeted therapies and/or ICI in CoM.

Summary

Through a collaborative effort of the Ophthalmic Oncology Group, we wish to perform a retrospective, multicenter, observational cohort study of patients with metastatic conjunctival melanoma treated with immune checkpoint inhibitors and/or targeted therapy. Patients will be identified by members of the OOG.

Aim/hypothesis

We hypothesise that patients with metastatic conjunctival melanoma have a similar outcome compared to patients with metastatic cutaneous melanoma when treated with targeted therapies and/or ICI.

Inclusion criteria

Patients with metastatic conjunctival melanoma, 18 years or older, receiving first-line or second-line immune checkpoint inhibitors and/or targeted therapy between 2012 and 2023 with a minimal follow up time of 3 years. Immune checkpoint inhibitors are defined as (combinations of) anti-PD1, anti-PD-L1 or anti-CTLA4 directed biologicals. Targeted therapy is defined as (combinations of) inhibitors of BRAF, MEK or receptor tyrosine kinases known to be involved in the pathogenesis of conjunctival melanoma (such as inhibitors of KIT, NRAS etc). The following patient and tumour

characteristics should be registered for all patients: age at first metastasis, gender, Eastern cooperative oncology group performance status (ECOG PS) at the start of systemic therapy, lactate dehydrogenase levels (LDH) at the start of systemic therapy, primary acquired melanosis (PAM) or Non-PAM associated at primary diagnosis, Breslow thickness at primary diagnosis, ulceration at primary diagnosis, mutation (BRAF, NRAS, NF1, triple-wt, other), lymph node metastasis, liver metastasis, brain metastasis, other site, number of organ sites with metastases, time from primary melanoma to metastatic disease, objective response rate according to RECIST 1.1 on ICI and/or targeted therapy, OS and PFS after start systemic therapy, and AJCC staging system 8th edition.

Outcome measures

This collaborative study aims to investigate the differences in objective response rate (ORR), progression-free survival (PFS), and overall survival (OS). Response evaluation should be in line with Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1.

Everyone that wishes to participate and include cases should contact the project leader by email in order to receive the link to the online datasheet for datasubmission. All collaborators that submit cases will be co-authors up to 3 persons participating per center. The project leaders will decide on first and last authorship.