Prospective Dutch cohort study of a primary melanoma gene-signature (CP-GEP model) to predict sentinel node status

No registrations found.

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

Summary

ID

NL-OMON24310

Source
NTR

Brief title
CP-GEP Implementation

Health condition

Melanoma (cutaneous)

Sponsors and support

Primary sponsor: SkylineDx
Source(s) of monetary or material Support: SkylineDx reimburses the extra pathology expenses

Intervention

Outcome measures

Primary outcome

CP-GEP test outcome (Note: as this is an implementation study, only descriptive data will be rendered)

Secondary outcome

Evaluation of subsequent care and health status

Study description

Background summary

Rationale: The management of cancer care during the COVID-19 pandemic is challenging. Management of newly diagnosed primary melanoma is one of these challenges. After the peak of the COVID-19 pandemic, it is anticipated that with the waiting lists of elective care there will be even more complexity of care delivery to allocate the adequate resources and adhere to current clinical guidelines. Globally, new guidance documents have been issued to support surgical triage that is required to dedicate resources to the patients that have the biggest medical need. This consortium has undertaken the immediate initiative to discuss how in their combined expertise guidance can be provided on how quality of care from a surgical perspective can be maintained without compromising on patient health outcomes. Our unified objective is to amend triage protocols and incorporate molecular diagnostics under strict conditions nationally to guide the transformation that will be required to manage the high demand on our health care system during and after the peak of the COVID-19 pandemic.

The objective of this consortium is to implement the CP-GEP model (Merlin Assay), a diagnostic tool, to triage patients according to their risk for nodal metastasis of their primary cutaneous melanoma to allow time dependent prioritization of sentinel lymph node biopsy (SLNB). An EORTC Melanoma Group study demonstrated that the time interval between primary melanoma excision and SLNB is not associated with survival in sentinel node positive patients. Patients with an increased risk for a positive SLN will be prioritized over patients with a low risk. The patients will be scheduled for a clinical assessment in their respective hospital within a maximum of 12 months after they have received the result of the diagnostic test. A test consisting of a gene expression profile (GEP) of the primary tumor combined with patient age and tumor Breslow thickness has been developed to allow identification of patients that safely may forgo SLN biopsy surgery due to their low risk for nodal metastasis. The GEP-based test has been developed for patients who are currently recommended for SLNB according to the American NCCN guidelines (Category T1a with adverse features, category T1b, category T2a and T2b, intermediate-thickness melanomas) to better triage patients for SLNB.

In Dutch practice, a SLNB is indicated with a Breslow Thickness above 0.8 mm. This study consortium states that a SLNB for pT1a is considered rare in the Netherlands. The test was developed on a representative cohort of invasive melanomas and the samples that were

used to develop the test were not subjected to any pre-processing steps (e.g. macrodissection). A robust multi-variate model including clinicopathological features was developed (CP-GEP model, Merlin Assay), and recently validated at the Erasmus MC. The result of the CP-GEP model could reduce immediate stress and anxiety with patients when they receive a low risk result. The patients that are considered to have an increased risk will be prioritized for elective SLNB over patients that have a low risk result. The patients with an increased risk as indicated by the CP-GEP model will follow the standard clinical guidelines and undergo a WLE + SLNB. This procedure might be deferred to later if the situation caused by the COVID-19 pandemic requires such in terms of risks and resources for undergoing surgery and/or (adjuvant) systemic therapy for SLN+ disease.

Objective: Implementation of an innovative diagnostic tool (CP-GEP model, Merlin Assay) to triage eligible patients according to the CP-GEP risk status of their primary cutaneous melanoma for prioritization of SLNB, allowing postponement of the SLNB to a moment in time at which elective surgery and provision of (adjuvant) systemic therapy is resumed in light of the current COVID-19 pandemic.

No intervention: Primary melanoma tissue that has already been acquired per routine practice guidelines to assess the diagnosis will be investigated. Patients who are eligible for SLNB will be asked informed consent to collect patient material and data.

Main study parameter: Successful implementation of the CP-GEP assay.

Data collection: Castor EDC.

Study objective

The CP-GEP assay can be implemented successfully in current clinical practice (in Dutch melanoma centers)

Study design

Baseline (CP-GEP outcome), 12 months

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

• Newly diagnosed melanoma of the skin after central pathology review.
• Male or female, age ≥18 years.
• Elected to undergo sentinel lymph node biopsy (pT1b – pT4) per the national Dutch guideline by the NVvH (Dutch Society of Surgery) published October 2019

Exclusion criteria

• Documented clinically positive nodes (N+) at diagnosis.
• Satellite or in-transit metastases.
• Multiple primary invasive melanoma mapping to the same draining lymph node basin.
• Distant metastatic disease (M1a,b,c) clinically present at primary diagnosis
• Documented prior history of a primary invasive melanoma of T1b or greater within the last 5 years.
• Ocular and mucosal melanomas and melanocytic tumors of uncertain malignant potential (MELTUMP) or (atypical) Spitz tumors.
• Full primary melanoma pathology report and diagnostic paraffin-embedded biopsy tissue unavailable.

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:	Pending
Start date (anticipated):	12-07-2020
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	09-07-2020
Application type:	First submission

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
NTR-new	NL8772
Other	METC Erasmus MC : METC-2020-0365

Study results