Minimal SN Tumor Burden (Minitub)

**Purpose**

The purpose of this registry is to collect data in order to discover whether melanoma patients with minimal SN tumor burden should undergo a complete lymph node dissection (CLND) or not.

Currently, if a patient has a positive (or metastatic) SN, this patient will be offered a CLND, which is a surgical intervention aiming to remove all lymph nodes from the same nodal basin as the SN. However, if the positive (or metastatic) SN is only minimally involved, some centers and/or countries do not offer a CLND routinely. As a matter of fact, the CLND procedure does not increase survival for patients with a minimal SN tumor burden, but can add prognostic information, potentially useful in the subsequent decision-making process. However, this is a surgical operation for the patient, which might be accompanied by significant side effects. Moreover, only approximately 20% of patients with a metastatic SN have further lymph node metastases in the same basin, which means that about 4 patients out of 5 will not benefit from a CLND. There is evidence that the same situation exists in melanoma as well, but this needs to be validated and this is why we are conducting this registry.

The results of this registry will be crucial to establish an accepted standard of care (CLND or nodal observation) for melanoma patients with minimal SN tumor burden.

**Condition**

Cutaneous Melanoma

**Study Type:** Observational [Patient Registry]

**Study Design:** Observational Model: Case Control

**Time Perspective:** Prospective

**Target Follow-Up Duration:** 5 Years

**Official Title:** Minitub: Prospective Registry of Sentinel Node (SN) Positive Melanoma Patients With Minimal SN Tumor Burden Who Undergo Completion Lymph Node Dissection (CLND) or Nodal Observation

**Primary Outcome Measures:**

- Distant Metastasis Free Interval (DMFI) [Time Frame: 5 years after last patient in] [Designated as safety issue: No]

**Secondary Outcome Measures:**

- Regional Control Rate (secondary endpoint): [Time Frame: 5 years after last patient in] [Designated as safety issue: No]
- Relapse Free Interval (RFI) [Time Frame: 5 years after last patient in] [Designated as safety issue: No]
- Melanoma Specific Survival (MSS) [Time Frame: 5 years after last patient in] [Designated as safety issue: No]
- Overall Survival (OS) [Time Frame: 5 years after last patient in] [Designated as safety issue: No]
- Morbidity: rates of wound infections, lymphedema and neurological damage [Time Frame: 5 years after last patient in] [Designated as safety issue: Yes]
Estimated Enrollment: 260  
Study Start Date: July 2009  
Estimated Primary Completion Date: July 2023 (Final data collection date for primary outcome measure)

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<td>Observation</td>
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<td>Complete Lymphnode Dissection</td>
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### Eligibility

#### Ages Eligible for Study: 18 Years and older (Adult, Senior)

#### Genders Eligible for Study: Both

#### Accepts Healthy Volunteers: No

#### Sampling Method: Non-Probability Sample

### Study Population
Patients with minimal SN tumor burden

### Criteria

#### Inclusion Criteria:
- 18 years of age or older
- Histological evidence of primary cutaneous melanoma
- Metastases solely confined within the SN:
  - In the sub-capsular space (with no parenchymal infiltration) and with a maximum diameter of the largest metastasis not greater than 0.4 mm or
  - Regardless of the site, any sub-micrometastasis with a maximum diameter not greater than 0.1 mm if there is more than 1 metastatic SN, the patient will be still eligible provided that all involved SN have minimal tumor burden, regardless of the amount of positive SNs and the interested basin

#### Exclusion Criteria:
- No history of any other malignancy within the past 5 years, except for non-melanoma skin cancer (Basal Cell Carcinomas or Squamous Cell Carcinomas) and in situ cervical cancer
- Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

### Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01942603

#### Contacts

Contact: Gaetan de Schaetzen +32 2 774 1618 gaetan.deschaetzen@eortc.be

#### Locations

**France**

- **CHRU de Lille**
  - Lille, France
  - Principal Investigator: Laurent Mortier
  - Recruiting
- **CHU de Nice - Hopital De L'Archet**
  - Nice, France
  - Principal Investigator: Lacour Jean-Philippe
  - Recruiting
- **Institut Gustave Roussy**
  - Paris, France
  - Principal Investigator: Andrea Cavalcanti
  - Recruiting

**Germany**

- **Charite - Universitaetsmedizin Berlin - Campus Mitte**
  - Berlin, Germany
  - Principal Investigator: Felix Kiecker
  - Recruiting
- **UniversitaetsMedizin Mannheim**
  - Mannheim, Germany
  - Principal Investigator: Jochen Utikal
  - Recruiting

**Italy**

[https://clinicaltrials.gov/show/NCT01942603](https://clinicaltrials.gov/show/NCT01942603)
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<th>Country</th>
<th>Institution</th>
<th>Recruiting</th>
<th>Address</th>
<th>Principal Investigator</th>
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<tr>
<td>Italy</td>
<td>Istituto Europeo di Oncologia</td>
<td>Recruiting</td>
<td>Milan, Italy</td>
<td>Testori Alessandro</td>
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<td>Italy</td>
<td>Istituto Nazionale Tumori IRCCS - Fondazione G. Pascale</td>
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<td>Napoli, Italy</td>
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<td>Spain</td>
<td>Hospital Clinic Universitari</td>
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<td>Lausanne, Switzerland</td>
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<td>Royal Bournemouth Hospital</td>
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<td>Norfolk And Norwich Hospital</td>
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<td>Norwich, United Kingdom</td>
<td>Marc Moncrieff</td>
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**Sponsors and Collaborators**
European Organisation for Research and Treatment of Cancer - EORTC

**Investigators**
Principal Investigator: Alexander van Akkooi, MD, PhD  The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis

**More Information**
- Responsible Party: European Organisation for Research and Treatment of Cancer - EORTC
- ClinicalTrials.gov Identifier: NCT01942603
- Other Study ID Numbers: EORTC-1208-MG
- Study First Received: September 11, 2013
- Last Updated: July 1, 2016
- Health Authority: Belgium: Ethics Committee, France: Committee for the Protection of Personnes, Denmark: Ethics Committee, Germany: Ethics Commission, Italy: Ethics Committee, Slovenia: Ethics Committee, Spain: Ethics Committee, Switzerland: Ethikkommission, Portugal: Ethics Committee for Clinical Research, Netherlands: Medical Ethics Review Committee (METC), United Kingdom: Research Ethics Committee, France: Agence Nationale de Sécurité du Médicament et des produits de santé
Keywords provided by European Organisation for Research and Treatment of Cancer - EORTC:
Minimal (SN) tumor burden
Stage III
Patients
Lymphnode Dissections

Additional relevant MeSH terms:
Melanoma
Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and Embryonal

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