

## Minimal SN Tumor Burden (Minitub)

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

Verified July 2016 by European Organisation for Research and Treatment of Cancer - EORTC

**Sponsor:**

European Organisation for Research and Treatment of Cancer - EORTC

**Information provided by (Responsible Party):**

European Organisation for Research and Treatment of Cancer - EORTC

**ClinicalTrials.gov Identifier:**

NCT01942603

First received: September 11, 2013

Last updated: July 1, 2016

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[History of Changes](#)

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[No Study Results Posted](#)

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### 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. Thus, there is an urgent need to identify which SN positive patients could be safely spared from a CLND. It has been demonstrated that breast cancer patients with minimal SN tumor burden can be safely managed with nodal observation only, without performing 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

### Resource links provided by NLM:

[MedlinePlus](#) related topics: [Cancer](#) [Melanoma](#)

[Genetic and Rare Diseases Information Center](#) resources: [Melanoma, Familial](#) [Carcinoid Tumor](#) [Neuroepithelioma](#)

[U.S. FDA Resources](#)

### Further study details as provided by European Organisation for Research and Treatment of Cancer - EORTC:

#### 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)

#### Groups/Cohorts

Observation

Complete Lymphnode Dissection

### ► 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](mailto:gaetan.deschaetzen@eortc.be)

#### Locations

##### France

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

##### Germany

Charite - Universitaetsmedizin Berlin - Campus Mitte Berlin, Germany Principal Investigator: Felix Kiecker	<b>Recruiting</b>
UniversitaetsMedizin Mannheim Mannheim, Germany Principal Investigator: Jochen Utikal	<b>Recruiting</b>

##### Italy

Istituto Europeo di Oncologia **Recruiting**  
Milan, Italy  
Principal Investigator: Testori Alessandro

Istituto Nazionale Tumori IRCCS - Fondazione G. Pascale **Recruiting**  
Napoli, Italy  
Principal Investigator: Corrado Caracò

Istituto Oncologico Veneto IRCCS - Ospedale Busonera **Recruiting**  
Padova, Italy  
Principal Investigator: Marco Rastrelli

#### Netherlands

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

Erasmus MC Cancer Institute - location Daniel den Hoed **Recruiting**  
Rotterdam, Netherlands  
Principal Investigator: Dirk Grunhagen

#### Poland

Maria Sklodowska-Curie Memorial Cancer Centre **Recruiting**  
Warsaw, Poland  
Principal Investigator: Piotr Rutkowski

#### Slovenia

The Institute Of Oncology **Recruiting**  
Ljubljana, Slovenia  
Principal Investigator: Marko Hocevar

#### Spain

Hospital Clinic Universitari **Recruiting**  
Barcelona, Spain  
Principal Investigator: Susana Puig

#### Switzerland

Centre Hospitalier Universitaire Vaudois **Recruiting**  
Lausanne, Switzerland  
Principal Investigator: Maurice Matter

#### United Kingdom

Royal Bournemouth Hospital **Recruiting**  
Bournemouth, United Kingdom  
Principal Investigator: Dexter Perry

Norfolk And Norwich Hospital **Recruiting**  
Norwich, United Kingdom  
Principal Investigator: Marc Moncrieff

#### 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  
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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

Neoplasms by Histologic Type

Neoplasms

Neoplasms, Nerve Tissue

Nevi and Melanomas

ClinicalTrials.gov processed this record on July 05, 2016