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
Last verified: July 2016
History of Changes

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 Lymfnode 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

Locations

France

CHRU de Lille — **Recruiting**
Lille, France
Principal Investigator: Laurent Mortier

CHU de Nice - Hopital De L'Archet — **Recruiting**
Nice, France
Principal Investigator: Lacour Jean-Philippe

Institut Gustave Roussy — **Recruiting**
Paris, France
Principal Investigator: Andrea Cavalcanti

Germany

Charite - Universitaetsmedizin Berlin - Campus Mitte — **Recruiting**
Berlin, Germany
Principal Investigator: Felix Kiecker

UniversitaetsMedizin Mannheim — **Recruiting**
Mannheim, Germany
Principal Investigator: Jochen Utikal

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

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Other Study ID Numbers:	EORTC-1208-MG
Study First Received:	September 11, 2013
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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	Neoplasms by Histologic Type
Neuroendocrine Tumors	Neoplasms
Neuroectodermal Tumors	Neoplasms, Nerve Tissue
Neoplasms, Germ Cell and Embryonal	Nevi and Melanomas

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