Sentinel Lymph Node Procedure in Testicular Germ Cell Tumour

Published: 24-08-2018
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Assessment of accuracy of sentinel node biopsy, defined as the false negative rate.

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON46792

Source
ToetsingOnline

Brief title
SENATOR

Condition

- Reproductive neoplasms male malignant and unspecified
- Haematological and lymphoid tissue therapeutic procedures

Synonym
testicular germ cell tumour; testicular cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Occult Metastasis, Sentinel Node, Testicular Germ Cell Tumor, Testicular

Neoplasms

Outcome measures

Primary outcome

The main study endpoint will be the false negative rate of sentinel node biopsy. False negative sentinel node rate will be calculated as follows: [number of patients with a false-negative sentinel node] / [total number of patients with tumor positive nodes]

Patients with a false-negative sentinel node are defined as patients of whom the sentinel nodes were negative on histopathological examination, but who develop a recurrence during follow-up. Recurrence can be assessed by CT-scanning, thoracic X-ray, and serum tumour markers.

Secondary outcome

Sensitivity and specificity of the sentinel node approach, recurrence rate, cancer specific and overall survival, percentage of occult lymph node metastases, extra operating time, number of adverse events, and morbidity.

Study description

Background summary

Current practice in patients with Clinical Stage I (CS I) testicular germ cell tumour is active surveillance after orchiectomy, with relapses occurring in 15-20% of patients. The majority of relapses occur in the lymh nodes as lymphogenic spread is the dominant route of dissemination. A sentinel node procedure, in which the sentinel lymph node is resected and pathologically examined, could be more reliable to identify patients who are likely to relapse. Early identification of patients with micrometastases in the sentinel node makes it possible to treat these patients at the earliest possible moment. Absence of metastases could lead in the future to a less intensive follow up

protocol than the present one.

Study objective

Assessment of accuracy of sentinel node biopsy, defined as the false negative rate.

Study design

This will be a multicenter prospective observational study.

All patients that are included will undergo a sentinel node procedure. The histology of the sentinel node will divide the patients in two groups: those who have occult lymph node metastases and those without lymph node metastases. Node negative patients will be observed by active surveillance.
Treatment of node positive patients will be at the discretion of the institute and treating medical oncologist. As the clinical significance of a sentinel node positive for occult metastases is currently unknown, this patient group will be closely monitored. If the treatment approach is insufficient for the node positive group, this treatment approach can be amended during the study.

Study burden and risks

Study participation will require patients to undergo a lymphoscintigraphy, single photo emission computed tomography with computed tomography (SPECT/CT) and an invasive procedure for the laparoscopic retrieval of the sentinel lymph node. This retrieval will take place in the same surgical session as the orchiectomy. Thus, no extra operating session is necessary.

The burden to the participant will be some (four to five) small scars, longer operating time and associated surgical risks (e.g. bleeding risk).
The immediate benefit for the participant will be knowledge of their sentinel lymph node status.

The benefit in the future will be earlier diagnosis, a lower rate of false-negative diagnosis, the possibility to treat metastatic patients (tumour positive sentinel node) at an earlier stage, and a change in the follow up (reduction of abdominal CT-scans and subsequently less exposure to radiation).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients suspected of testicular germ cell tumour, based on physical examination, ultrasound imaging, and tumour markers
Patients 18 years and older
No evidence of metastases on first staging (thoraco-abdominopelvic CT)
Written and signed informed consent

Exclusion criteria

Patients with evidence of metastases at first staging
Patients with a second primary tumour
Patients with recent (< 6 months before diagnosis) surgical treatment to the external genitals or recent surgical intervention in the inguinal or retroperitoneal regions
Patients with previous abdominal surgery, necessitating open surgical approach for the sentinel node biopsy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	87
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-08-2018
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
ClinicalTrials.gov	NCT03448822
CCMO	NL62350.031.18