Feasibility of lymphoscintigraphy and sentinel node biopsy in patients with renal cell carcinoma

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The objective of the study is to determine the feasibility of lymphatic mapping in non-metastatic, clinically node negative RCC including preoperative lymphoscintigraphy and intraoperative sentinel node identification using patent blue dye and a...

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30718

Source
ToetsingOnline

Brief title
Sentinel node procedure in kidney cancer

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
kidney cancer, renal cell carcinoma

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: Feasibility, lymphoscintigraphy, renal cancer, sentinel node

Outcome measures

Primary outcome

Feasibility of a) preoperative lymphoscintigraphy and b) intraoperative

detection and sampling of the sentinel node.

Secondary outcome

Excised sentinel nodes will be examined for activation and/or downregulation of

immune cells in comparison to non-sentinel nodes.

Study description

Background summary

Nowadays, sentinel node biopsy is widely used for nodal staging of melanoma and breast cancer. Other investigators performed sentinel node biopsy in urological malignancies, head and neck cancer and gastrointestinal cancer.
Currently, little is known about the lymphatic drainage of renal cell carcinoma. This may have implications for the fact that the role of lymph node dissection in renal cell carcinoma has been controversial for decades.
Next to the importance for lymph node dissection, the sentinel node has been recognized as the lymph node in which priming of the immune reaction takes place. There are detailed investigations in melanoma, an immunogenic malignancy like renal cell carcinoma. Sentinel lymph nodes, being the first nodes to receive lymph from a primary tumour and the preferential site of initial tumour metastases, are intensively exposed to the bioactive products of tumour cells and other associated cells. This makes them ideal for studies of the factors that determine selective tissue susceptibility to metastases.

Study objective

The objective of the study is to determine the feasibility of lymphatic mapping in non-metastatic, clinically node negative RCC including preoperative lymphoscintigraphy and intraoperative sentinel node identification using patent blue dye and a gamma ray detection probe

Study design

Feasibility study. To gain sufficient experience with the injection technique and intraoperative sampling during a feasibility study, a total number of 10 patients will be included in this study.
No statistical analysis is required.

Intervention

On the day before surgery or at least four hours pre-operatively, 99mTc-nanocolloid will be injected at the primary tumour site. The injection will be performed percutaneously under ultrasound or CT guidance. Subsequently, lymphoscintigraphy will be performed at 20 minutes, 2 hours and 4 hours after tracer injection. During the last scintigraphy, emission-transmission SPECT will be performed. These images will be matched with CT to determine the anatomical localization of the sentinel node. The operation will be planned in the afternoon or the following day depending on logistic aspects.
Patent blue dye (small volume of 0.5 ml) will be injected near the primary tumour as soon as the kidney is exposed at surgery. A standard nephrectomy will be performed. Blue stained lymph nodes will be dissected and the hand-held gamma probe will be used to identify radioactive lymph nodes.

Study burden and risks

Apart from an extra time of 2 1/2 hours and a lymphoscintigraphy the additional risks associated with participation (intratumoral injection and intraoperative sampling) are minor in comparison to the risk of nephrectomy (standard therapy)

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

1. Localized parenchymal tumor of the kidney not exceeding 10 cm (cT1-cT2)
2. No metastatic disease on imaging and clinical examination (cN0, cM0)
3. Age: 18 to 65 years
4. Life expectancy > 3 months
5. WHO performance status 0 or 1 and fit for surgery
6. Written informed consent obtained from the patient after having been informed about the objectives of the study and the medication used.
7. Blood counts: Leucocytes > 3.0 x 109/l, platelets > 100 x 109/l, hemoglobin > 6.0 mmol/l.
8. Serum bilirubin, ASAT, ALAT and creatinin within 1.5 times of upper limit of reference values of laboratory.
9. No prior systemic treatment with biological response modifiers, tyrosine-kinase inhibitors, monoclonal antibodies or chemotherapy.

Exclusion criteria

1. Parenchymal kidney tumor larger than 10 cm
2. clinically metastatic disease or at imaging
3. Patients in whom surgery is no option due to comorbidity
4. Current cardiovascular disease, hematopoetic, pulmonary, hepatic or renal dysfunction or WHO performance status > 1.
5. Previous immunotherapy, therapy with tyrosine-kinase inhibitors, monoclonal antibodies or chemotherapy.
6. Corticosteroid and/ or other immunosuppressive therapies.
7. Prior malignancies. In case of NED the period should be > 5 years.
8. Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

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
CCMO	NL16017.031.07