Site and distribution of sentinel lymph nodes in renal cell carcinoma. A diagnostic study.

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To investigate site and distribution of sentinel nodes in clinically non metastatic kidney cancer.

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

Summary

ID

NL-OMON33464

Source
ToetsingOnline

Brief title
Site and distribution of sentinel lymph nodes in renal cell carcinoma.

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)

Synonym
kidney tumour, renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI/AVL

Intervention

Keyword: renal cell carcinoma, sentinel node

Outcome measures

Primary outcome

*Main endpoint: Lymphatic drainage not localized locoregional

retroperitoneally.

Secondary outcome

*Secondary endpoints: Intra-operative mapping and detection, activation or

downregulation of immune cells in sentinel nodes, cancer specific survival and

morbidity, complication rate of surgery, sensitivity of the technique and stage

migration.

Study description

Background summary

The aim of the study is to analyze lymphatic drainage from kidney tumours and to describe the distribution of sentinel nodes. Our hypothesis is that sentinel nodes are not exclusively localized locoregional retroperitioneally.

Study objective

To investigate site and distribution of sentinel nodes in clinically non metastatic kidney cancer.

Study design

Diagnostic study.
Intervention:
*Pre-operative lymphoscintigraphy, after injection of 240 MBq of 99mTechnetium-nannocolloid. Planar images after 20 minutes, 2 hours and 4 hours. SPECT/CT after 4 hours.
*Intra-operative sentinel node excision (during the *standard* nephrectomy)

after localization with patent blue and/or gamma probe.

Intervention

Lymphoscintigraphy after injection of the radiopharmaceutical. During nephrectomy, a sentinel node biopsy will be performed.

Study burden and risks

Burden and risks: Radioactivity dose is the same as in other malignancies and does not have any risks. Patent blue is registered in the Netherlands, allergic reactions are extremely rare and airway and intravenous access are secured during administration. Injection might cause a kidney bleeding, but since patients will be operated afterwards it will not have serious implications. Sentinel nodes will not be excised if excision will lead to a substantial longer operation time (more than half an hour) or a increase in operation risk. This means that retroperitoneal sentinel nodes will be excised, as will be superficial supraclavicular sentinel nodes, but sentinel nodes in the thoracic cavity will be left in place.
Possible benefits: It is not clear whether early detection of sentinel node metastasis can provide survival benefit. Patients might have a benefit of optimal staging and possibly early resection in case of a small localized metastasis in the sentinel node.

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-cT3)
2. No metastatic disease on imaging and clinical examination (cN0, cM0)
3. Age: 18 years and older
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. 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. Preganancy.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL26406.031.08