Utilizing magnetic nanoparticles in prostate cancer for sentinel and aberrant lymph node mapping

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON50068

Source
ToetsingOnline

Brief title
Extensive sentinel lymph node mapping

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
lymph node metastases, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitieit Twente
Source(s) of monetary or material Support: NWO-TTW

Intervention

Keyword: Lymphnode, Prostate, Prostatecancer, SPION

Outcome measures

Primary outcome

There are two main study parameters: (1) identification of LNs with magnetic particles based on the pre-operative Sentimag inspection and MRI-scan and (2) pathological research of all dissected lymph nodes to correlate if lymph nodes with metastases also contain magnetic particles.

Secondary outcome

There are several secondary study parameters. The main secondary study parameter is the identification of LNs containing magnetic particles with the DiffMag detector, and to compare this with the Sentimag® detector, thus proving the feasibility of the new prototype detector. Both detectors will also be compared with the pathological results (do detected LNs also contain magnetic tracer). To summarize we register the following secondary parameters:

- Proportion of LNs where the magnetic tracer could be detected with the DiffMag detector (detection rate DiffMag detector), of all dissected LNs
- Proportion of LNs where the magnetic tracer could be detected with the Sentimag® detector (detection rate Sentimag® detector), of all dissected LNs
- False positive rate for both detectors (detector measures magnetic tracer, but none is pathological found)
- False negative rate for both detectors (detector does not measure magnetic tracer, but is pathological found)

Additional secondary study parameters:

- Total amount of injected SPIONs

- Exact time between injection and operation

- Proportion of LN which could still be visualized on the post-operative MRI

(missed LNs)

- Total operating time

Other registered parameters:

- Age

- Sex

- Height/weight (BMI)

- Use of medicine

- Type, location and size of cancer

Study description

Background summary

Patients diagnosed with a prostate tumour but without visible metastases on imaging modalities can still have small metastases in the local lymph nodes. To discover and possibly treat this the tumour and (on indication) all surrounding lymph nodes are surgically removed. However, in 54-96% of the prostate cancer patients no metastases were found in the resected pelvic lymph nodes. Also in 26-56% of patients tumour draining lymph nodes lie outside the usual resection area. For this reason the first step to improve this procedure should be to increase the available information by performing extensive lymph node mapping. For mapping lymph nodes a radioactive tracer is currently used as gold standard in breast cancer patients. The radioactive tracer has four known disadvantages; (1) limited availability, (2) strict rules and regulations, (3) degradation time and (4) radioactive load for user and patient. Another option is using a magnetic tracer such as Magtrace®. This tracer can be found intraoperative

through a magnetic detector and beforehand through an MRI-scan.

Study objective

The primary goal is to increase the available information for the surgeon by providing an extensive lymph node map of the patient. The secondary goal is to compare two magnetic detectors for the further development of a laparoscopic version. The final studygoal is to develop a laparoscopic sentinel node procedure for prostate cancer patients.

Study design

This is a prospective, interventional, single centre pilot trial, with the main goal to increase the available information made to maximize outcome. Also a comparison between a CE approved first generation magnetic detector (the Sentimag®) with a new prototype second generation magnetic detector (the DiffMag) in an ex vivo study setup will be done for the further development of a laparoscopic magnetic detector.

Intervention

Patients will receive a pre-operative and post-operative MRI-scan and a pre-operative magnetic tracer injection around the tumour.

Study burden and risks

Burden: Additional local interstitial injections with magnetic tracer. Additional Sentimag® inspection pre-operative. Additional magnetic resonance imaging pre-operative and post-operative.
Risks & benefits: It could very well be that the current resection area is not adequate. This research will verify this and can be used as input for further research to optimise prostate cancer treatment.

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

Adults 18 years and older with a >=cT1N0M0 cinically significant prostate tumour classification and who are scheduled for a prostatectomy

Exclusion criteria

Contra-indications for robot assisted laparoscopy, intolerance/hypersensitivity to iron or dextran compounds or Magtrace®, patients with an iron overload disease, patients with pacemakers or other implantable devices in the chest wall and/or lower body. Also prostate cancer patients without excessable rectum

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Magtrace®
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-11-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL67624.091.19