Accuracy of lymph node imaging in prostate cancer: A prospective cohort study to determine the concordance between two imaging modalities, *Combidex* magnetic resonance imaging (Nano MRI) and 68Ga-PSMA positron emission tomography (PET).

Published: 07-03-2016
Last updated: 17-04-2024

1. To compare the following imaging technologies to the current practice of histology of pelvic lymph node dissection: a. PSMAGa68 PET b. Nano MR Lymphography and an enhanced arterial map (Nano MRL / EAM) to locate the position of the lymph nodes2....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON45969

Source
ToetsingOnline

Brief title
MAGNIFI

Condition

- Metastases

Synonym
Prostate cancer; Lymph node metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Astellas Pharma,Subsidie (Astellas)

Intervention

Keyword: lymph node, MRI, Prostate, PSMA-PET

Outcome measures

Primary outcome

Diagnostic

-Concordance of Ga68PSMA and Nano MRL

-Histology of LND

-Concordance of (a) and (b)

-Results of reimaging after LND

-Predict Ga68PSMA local tumor aggressiveness

Therapeutic

-Response to treatment * return to negative testing.

Secondary outcome

Not applicable.

Study description

Background summary

Following curative intended therapy in prostate cancer patients, a high proportion of patients (approx. 25%) relapse with local and/or distant

recurrence [1]. The metastasis of a lymph node (LN) in a patient with prostate cancer means that the disease has become systemic with the increased risk of disease progression. Therefore the ability to detect the presence of LN metastasis is important in terms of disease prognosis and treatment options. In the past, patients with LN metastasis have had poor prognoses due to the scarcity of accurate staging techniques and toxic treatment regimens such as radiotherapy. For those patients with a medium to high risk of having LN metastasis, the current procedure is a bilateral pelvic lymph node dissection (PLND). This is the standard procedure prior to curative treatment with either radical prostatectomy or radiation therapy. However, the procedure is not optimal due to the frequent inability to remove all positive lymph nodes within the dissection area. 41% of metastatic LN disease is not found [2], due to these LN being outside the routine surgery field. As a result, some urologists will perform an extended lymphadenectomy (e-PLND), which leads to extended operating times and the risk of complications [3]. Also, therapy of LN metastases has limitations: more than 50% of metastatic LN are outside the routine (RTOG-CTV) radiation field [4]. Thus the effect of standard LN radiotherapy is limited [5]. Currently used imaging techniques such as CT and conventional MRI are also not sensitive enough to detect prostate cancer metastases due to the small size of the nodes (< 8mm) [6]. Finally, 11C-Choline PET/CT fails to detect metastatic LN, when they are smaller than 6 mm [7] since a minimum amount of tracer needs to be present in the LN to be detected.

However, patients with metastatic LN *8 mm have a significantly better 5-year distant metastases-free (79% vs 16%) and overall survival (81% vs 36%), than patients with larger positive lymph nodes [8]. Thus detection and localization of most small LN and subsequent focused, patient tailored treatment of these small metastatic LN may reduce side effects and enable cure [9-10].

An accurate non-invasive imaging modality in combination with existing treatment techniques, may lead to a therapeutic shift for patients who have in the past been restricted to palliative treatment. Recently developed imaging modalities to detect small lymph node metastases, which offer promise, include Nano Magnetic Resonance (Combidex) Lymphography (Nano MRL) and 68Gallium-Prostate Specific Membrane Antigen (PSMA) Positron Emission Tomography Imaging (68Ga-PSMA PET).

Study objective

1. To compare the following imaging technologies to the current practice of histology of pelvic lymph node dissection:
a. PSMAGa68 PET
b. Nano MR Lymphography and an enhanced arterial map (Nano MRL / EAM) to locate the position of the lymph nodes

2. Determine whether CONCORDANCE of these two imaging technologies (PSMAGa68 PET - functional imaging, and Nano MR - anatomical imaging) is worse, better or

equal to lymph-node dissection, the current gold standard

Study design

This study will be a prospective, one arm, non-randomised cohort study, conducted at the Radboud University Medical Centre, Nijmegen, NL.

Study burden and risks

See paragraph E9. The nature and extent of the risks for participation in this study according to the 'Normenkader' (NFU) is supposed to be negligible.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male, aged 18 years (or older, if required by local law);- Prostate cancer present (Gleason * 7) and/or PSA * 15 and/or Clinical or radiological Stage T3;- Suspected lymph node involvement pre-prostatectomy ;- Suitable for pelvic lymph node dissection, as per institutional guidelines and not yet treated for prostate cancer;- Subject is willing to sign and date the study Informed Consent form;- Signed, written informed consent

Exclusion criteria

- Previous treatment for prostate cancer (surgery, radiotherapy, chemotherapy, hormone androgen deprivation therapy);- Proven metastatic disease;- Patients who refuse pelvic lymph node dissection;- Patients who refuse to join the trial or are unable to consent;- Patients not being considered for further therapy ;- Contra-indication to MRI scanning, IV iron infusion, allergy to dextran or other injectable contrast media used in this trial ;- Patients who cannot lie still for at least 30 minutes or comply with imaging;- Unequivocal evidence of disease outside the pelvis on conventional imaging ;- Subject has medical conditions that would limit study participation (per physician discretion);- Subject has hemochromatosis and liver disease;- Subject has known allergy against Fe-products or dextranes;- Subject is enrolled in one or more concurrent studies that would confound the study results of this study as determined by the study investigators;- Subject meets the exclusion criteria required by local law

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2017
Enrollment:	80

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[Ga68]-PSMA
Generic name:	[Ga68]-PSMA
Product type:	Medicine
Brand name:	FERUMOXTRAN-10
Generic name:	FERUMOXTRAN-10

Ethics review

Approved WMO Date:	07-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-11-2017
Application type:	Amendment

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
EudraCT	EUCTR2015-005016-15-NL
CCMO	NL55589.091.16