Application of PET-MR- a diagnostic accuracy study of combined dwMRI and 18F-Choline PET-CT for baseline staging of prostate cancer validated by extended laparoscopic lymph node dissection.

Published: 26-05-2011
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To compare the diagnostic performance of new lymph node staging methods for prostate cancer (dwMRI fused with 18F-Choline PET-CT) with the current gold standard of staging, the extended pelvic lymph node dissection (ELND)

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

Summary

ID

NL-OMON39287

Source
ToetsingOnline

Brief title
PET-MR for prostate cancer staging

Condition

- Metastases
- Genitourinary tract disorders NEC
- Renal and urinary tract therapeutic procedures

Synonym
prostate cancer

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: LPT gelden

Intervention

Keyword: lymph node dissection, MRI, PET, Prostate cancer

Outcome measures

Primary outcome

Findings of ELND will serve as the reference standard. Analysis of PET-MR and lymph node dissections will be performed both on a per-region and per-patient basis. Patient- and region-based sensitivity and specificity of PET-MR will be calculated. In addition, the complication rate of ELND will be determined after 3 months follow-up.

Secondary outcome

In addition, the complication rate of ELND will be determined after 3 months follow-up.

Study description

Background summary

Numerous studies have shown that a classic, limited laparoscopic pelvic lymph node dissection was inadequate in staging patients with prostate cancer. In these studies it was proven that the extended lymph node dissection revealed in up to 40% metastases outside the area of the classic lymph node dissection and thus much more accurate for staging. However, this extended operation is associated with an increased rate of complications such as (infected) lymphocele, lymphorrhoea and postoperative haemorrhage. Hence there is need for less invasive lymph node staging for prostate cancer. Recently choline based radiotracers in conjunction with PET as well as diffusion-weighed MRI

have been introduced for staging and restaging of prostate cancer.

Study objective

To compare the diagnostic performance of new lymph node staging methods for prostate cancer (dwMRI fused with 18F-Choline PET-CT) with the current gold standard of staging, the extended pelvic lymph node dissection (ELND)

Study design

A prospective single-center diagnostic accuracy study

Study burden and risks

Burden and risks of participation to this study are relatively small.

Contacts

Public
Isala Klinieken

Groot Weezenland 20
Zwolle 8011JW
NL
Scientific
Isala Klinieken

Groot Weezenland 20
Zwolle 8011JW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

1. Age 18-80
2. Written informed consent
3. Biopsy proven prostate cancer cT1-T3 Nx M0
4. A chance of more than 15% of having lymph node metastases

Exclusion criteria

1. Neo-adjuvant treatments for prostate cancer .
2. Severe claustrophobia
3. Any metal prosthesis or device

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-11-2011
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2011

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL36042.075.11