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Measurement of variation in imaging report findings for 68Ga-PSMA-11 PET/CT in patients with prostate cancer: an international study with participation of multiple centers

Submission date 13/10/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 27/10/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/01/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
68Ga-PSMA-11 PET/CT is a new imaging technique developed to use for investigating how advanced a cancer is and where it is located. It can be used, for example, to monitor the response of a cancer to radiotherapy. The overall value of a imaging technique such as this depends on the degree of reader agreement – that is, if a number of people agree on what the image is showing. Knowing how different people will interpret the same image (interobserver variability) and how many people will agree that it shows the same thing (reproducibility) is essential for interpreting the results of studies and for designing new studies. The aim here is to determine interobserver agreement for 68Ga-PSMA-11 PET/CT interpretations for prostate cancer and to compare the findings among highly experienced and less experienced readers.

Who can participate?
Nuclear medicine physicians or radiologists with PET/CT experience.

What does the study involve?
Participants are given 68Ga-PSMA-11 PET/CT images from anonymous patients with prostate cancer and, upon a visual inspection, are asked to report on their findings using a standard template. They are asked to interpret what they see from a number of images of lymph nodes affected by localized prostate cancer and divided into different regions or sections. The participants are asked to judge whether each image they see shows prostate cancer. The results are compared to that of histopathology and follow-up imaging taken for all the patients more than six months before the 68Ga-PSMA-11 PET/CT imaging. Interobserver agreement between participants is assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Department of Nuclear Medicine, Ludwig-Maximilians-University Munich (Germany)

When is the study starting and how long is it expected to run for?
October 2016 to March 2017

Who is funding the study?
Department of Nuclear Medicine, Ludwig-Maximilians-University Munich (Germany)

Who is the main contact?
Dr Wolfgang Fendler

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13102016.1.0

Study information

Scientific Title
68Ga-PSMA-11 PET/CT interobserver agreement for prostate cancer assessments: an international multicenter prospective study

Acronym
PSMAGREE

Study objectives
The overall value of an imaging method is associated with the degree of reader agreement. Knowledge of interobserver variability and reproducibility is therefore essential for interpreting

study results and design of future trials. The aim of this study is to determine interobserver agreement for interpretations of 68Ga-PSMA-11 PET/CT and to compare findings among readers with low and high levels of experience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Ludwig-Maximilians-University Munich, 10/06/2016, ref: 594-16UE

Study design
Observational

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Anonymized PET/CT images of 50 patients included in the study (one scan per patient) will be electronically submitted to more than ten nuclear medicine physicians/radiologists from Europe, Asia, Australia or North America. Data include standard DICOM files of CT and attenuation-corrected PET images.

All reader report a visual interpretation of the 68Ga-PSMA-11 PET/CT image datasets using a standard template. Visual interpretation will be performed for locoragional lymph nodes - divided into pelvic regions, extra-pelvic lymph nodes, bone and visceral organs. Each region will be judged positive or negative for prostate cancer involvement.

For binary data, agreement among each observer and the reference reader will be evaluated using Cohen's κ. Overall agreement using pooled observer data will be evaluated using generalized estimation equations. For non-binary data, agreement among all observers was evaluated by intraclass correlation coefficient (ICC) using two-way mixed model for absolute agreement (single measures). Ninety-five percent confidence intervals (CIs) are reported for κ and ICC values. Interpretation of κ and ICC will be based on a classification provided by Landis and Koch: 0.0, poor; 0.0–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; 0.81–1.00, almost-perfect reproducibility. Discrepancies in quantitative ratings among observers will be expressed as mean difference (Δ) ± standard deviation (SD). Sensitivity, specificity, positive predicive value, and negative predicive value will be calculated for each observer

Histopathology and follow-up (PSA and imaging) obtained for all patients more than six months before the index test serves as reference standard. Lymph nodes regions, organs and bone will be judged positive or negative for prostate cancer involvement based on the results from histopathology and follow-up imaging.

Intervention Type
Device

Primary outcome measure
Interreader agreement, i.e. the variance between imaging findings of different readers, calculated by Cohen's κ.

Secondary outcome measures
1. Accuracy for each observer compared to the reference standard, determined by sensitivity, specificity, positive predicive value, and negative predictive value
2. Comparison of accuracy between readers of low and high levels of experience, by difference in pooled sensitivity, specificity, positive predictive value, and negative predictive value

Overall study start date
13/10/2016

Completion date
01/03/2017

Eligibility

Key inclusion criteria
Nuclear medicine physician or radiologist with PET/CT experience.

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
16

Total final enrolment
16

Key exclusion criteria
Physicians with prior knowledge of the included patient datasets.

Date of first enrolment
01/11/2016

Date of final enrolment
13/12/2016

Locations

Countries of recruitment
Australia

Austria

Denmark

France

Germany

Japan

United States of America

Study participating centre
Department of Nuclear Medicine, Ludwig-Maximilians-University Munich
Klinik und Poliklinik für Nuklearmedizin
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Study participating centre

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Study participating centre
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Study participating centre
University Hospital of Würzburg
Department of Nuclear Medicine
Würzburg
Germany
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Sponsor information

Organisation

Department of Nuclear Medicine, Ludwig-Maximilians-University Munich

Sponsor details
Klinik und Poliklinik für Nuklearmedizin
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05591te55

Funder(s)

Funder type
University/education

Funder Name
Department of Nuclear Medicine, Ludwig-Maximilians-University Munich

Results and Publications

Publication and dissemination plan
Results (Cohen's κ, intraclass correlation coefficient, sensitivity, specificity, positive predicitive value, negative predictive value, accuracy) will be published within three to six months of completion of the trial.

Intention to publish date
01/03/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/04/2017	07/01/2022	Yes	No