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FDG-PET/CT alters treatment in node-positive penile cancer

Submission date 23/05/2023	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/06/2023	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 01/08/2025	**Condition category** Cancer	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Screening for metastases (cancer that has spread) with a CT scan of the thorax and abdomen has a limited sensitivity (20-38%). The added value of investigating patients at risk for locoregional (localized region of the body) and distant spread, as well as screening for synchronous malignancies, is not known. However, for pelvis lymph nodes higher sensitivity has been reported for PET/CT in penile cancer. Findings also suggest that the fluorodeoxyglucose positron emission tomography/computed tomography (FDG-PET/CT) scan and sentinel node biopsy might have a complementary value. The aim of this study is to find out whether FDG-PET /CT has practical implications in the care of patients with advanced penile cancer and nodal metastases and alters treatment compared to ordinary staging with a CT scan.

Who can participate?
Patients aged 18 years and over with node-positive penile cancer in Sweden

What does the study involve?
Participants undergo FDG-PET/CT to investigate the proportion of patients subjected to altered treatment based on the FDG-PET/CT findings.

What are the possible benefits and risks of participating?
Based on additional information on the extent of the disease, treatment could be altered according to additional information gained by FDG-PET/CT. Risks include additional confirmatory studies and tissue samples that might be necessary in relation to the FDG-PET/CT findings, and consequently a prolonged time to treatment start.

Where is the study run from?
Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
December 2019 to March 2029

Who is funding the study?
Skåne University Hospital (Sweden)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
NoDe-pOsitive penile cancer and FDG-PET/CT – does PET modify treatment? (DO PET)

Acronym
DO PET

Study objectives
Fluorodeoxyglucose positron emission tomography/computed tomography (FDG-PET/CT) in patients with advanced penile cancer with nodal metastases alters treatment compared to ordinary staging with CT.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 21/02/2020, Etikprövningsmyndigheten (Box 2110, SE750 02 Uppsala, Sweden; +46 (0) 10 457 08 00; registrator@etikprovning.se), ref: Dnr 2019-04456 and 2020-02375

Study design
Prospective multicenter trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The researchers prospectively apply FDG-PET/CT in all penile cancer patients with node-positive disease to investigate the proportion of patients subjected to altered treatment based on the FDG-PET/CT findings.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
FDG-PET/CT

Primary outcome(s)
Altered treatment according to FDG-PET/CT findings, measured using FDG-PET/CT discussions at multidisciplinary team (MDT) prior to planning definitive treatment

Key secondary outcome(s))
Sensitivity for detection of iliac lymph node metastases, measured using FDG-PET/CT discussions at multidisciplinary team (MDT) prior to planning definitive treatment

Completion date
01/03/2029

Eligibility

Key inclusion criteria
Node-positive penile cancer (cN+ or cN3 after sentinel node biopsy)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Age below 18 years

Date of first enrolment
27/02/2020

Date of final enrolment
01/03/2029

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital
Department of Urology
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Study participating centre
Örebro University Hospital, Örebro
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Sponsor information

Organisation
Skåne University Hospital

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Skånes universitetssjukhus

Alternative Name(s)
Skåne University Hospital, SUS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

Results and Publications

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