

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

<b>Submission date</b> 23/05/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/06/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/08/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?  
Fredrik Liedberg, fredrik.liedberg@med.lu.se

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Fredrik Liedberg

### ORCID ID

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### Contact details

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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](mailto: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**

Department of Urology

Södra Grev Rosengatan

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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes