# Trial Description

## Title

**Diagnostic performance of Prostate HistoScanningTM (PHS) in men at risk of prostate cancer scheduled for an initial prostate biopsy.**

## Trial Acronym

**PHSTT-01**

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**The primary objective of the PHSTT-01 trial is to determine if prostate HistoScanning (HS) analysis can be used improve the detection of clinically significant prostate cancer (PCa), and potentially reduce the burden and number of biopsies in routine clinical practice. Prostate HS is an ultrasound-based tissue characterization technology specifically developed to detect, visualize, and locate tissue suspected of harboring PCa. These suspicious tissues are displayed as red areas on an imaging monitor. Recently a new biopsy guidance tool has been developed that uses the results of the prostate HS analysis.**
**The subjects that will participate in this study are all scheduled for a first biopsy of the prostate. They will initially be imaged using transrectal ultrasound (TRUS) to obtain data for prostate HS analysis. The results of HS analysis will be used later in the procedure. Subjects will then undergo a routine systematic 10- to 12-core biopsy procedure using TRUS. This will be followed by a TRUS-guided biopsy that uses the result of prostate HS analysis and new biopsy guidance tool.**

## Brief Summary in Scientific Language

**PHSTT-01 is a multi-center, prospective clinical trial to evaluate the diagnostic performance of prostate HS analysis in men at risk of PCa that have been scheduled for a first prostate biopsy. The purpose of this study is to determine if prostate HS analysis can improve the detection of clinically significant PCa, and potentially reduce the burden and number of biopsies in routine clinical practice. Subjects are men with serum total prostate-specific antigen (PCA) <= 20ng/mL (<= 10ng/mL if taking the 5-alpha reductase inhibitor).**
**In a single visit, subjects will first be imaged with TRUS for the purpose of generating data for prostate HS analysis. The results of HS analysis will be used later in the procedure. Subjects will then undergo two consecutive biopsy procedures. First, using TRUS, a systematic 10- to 12-core biopsy procedure will be performed. In turn, prostate HS data taken at the beginning of the procedure will be used to determine suspicious areas (displayed as red on an imaging monitor) and used to guide the biopsy procedure. Areas that are identified as suspicious (zero to a maximum of 3 areas) will then be sampled with two biopsy cores. Depending on the number of suspicious areas identified by prostate HS,**

**the number of cores will be zero to a maximum of 6 cores.**

## Organizational Data

- DRKS-ID: **DRKS00005263**
- Date of Registration in DRKS: **2014/03/13**
- Date of Registration in Partner Registry or other Primary Registry: **2013/09/19**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK-BR-78/13-1 , Ethikkommission bei der Sächsischen Landesärztekammer**

## Secondary IDs

- Primary Registry-ID: **NCT01950871 (ClinicalTrial.gov)**

## Health condition or Problem studied

- Free text: **Subjects suspected to have PCa who are schedules for a first prostate biopsy.**
- ICD10: **C61 - Malignant neoplasm of prostate**

## Interventions/Observational Groups

- Arm 1: **Prostate HistoScanning (HS) analysis with HS-guided biopsy will used to sample two cores per suspicious area (displayed as red on an imaging monitor), up to a maximum of 3 suspicious areas per subject. Depending on the number of suspicious areas identified by prostate HS, the number of cores will be zero (if no suspicious area is identified) up to a maximum of 6 cores.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Screening**
- Assignment: **Single (group)**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Screening**

Assignment: **Single (group)**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Diagnostic performance of prostate HS to identify clinically significant PCa using prostate biopsy histology from systematic biopsy as reference: receiver operating characteristic (ROC) curve, area under the ROC curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV).**

### Secondary Outcome

**Diagnostic performance of prostate HS to identify PCa using prostate biopsy histology from systematic biopsy as reference: receiver operating characteristic (ROC) curve, area under the ROC curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV).**

**Diagnostic performance of prostate HS to identify clinically significant PCa using a combination of outcomes of both systematic biopsy and HS guided biopsy histology as reference: receiver operating characteristic (ROC) curve, area under the ROC curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV).**

**Difference in detection rates of clinically significant PCa between systematic and prostate HS guided biopsy.**

## Countries of recruitment

- BE **Belgium**
- DE **Germany**
- NL **Netherlands**
- LT **Lithuania**
- LV **Latvia**

LV **Latvia**

- HU **Hungary**
- FR **France**
- IT **Italy**
- UK **United Kingdom**
- EE **Estonia**
- CZ **Czech Republic**
- BG **Bulgaria**
- AT **Austria**
- RU **Russian Federation**
- ES **Spain**
- CH **Switzerland**
- TR **Turkey**
- DK **Denmark**

## Locations of Recruitment

- University Medical Center **Cliniques Universitaires Saint Luc, Brussels**
- University Medical Center **UZ VUB, Brussels**
- Medical Center **Onze Lieve Vrouw Ziekenhuis OLVZ, Aalst**
- Medical Center **Paracelsus Klinik, Düsseldorf**
- Medical Center **PAN Klinik, Köln**
- Medical Center **Klinikum Wolfsburg Urologie, Wolfsburg**
- Medical Center **Cancer Center - Prostatazentrum, Braunschweig**
- Medical Center **St. Elisabeth Krankenhaus, Leipzig**
- Medical Center **Martini Klinik - Prostate Cancer Center, Hamburg**
- Medical Center **Klinikum Herford, Herford**
- Medical Center **Klinikum Leverkusen, Leverkusen**
- Medical Center **Antoni Van Leeuwenhoek Ziekenhuis - Nederlands Kanker Instituut, Amsterdam**
- University Medical Center **Vilniaus Universiteto Onkologijos Institutas - Santariškiu Clinics , Vilnius**
- Medical Center **URO, Riga**
- Medical Center **Uro-Clin Ltd., Pécs**
- Medical Center **Institut Mutualiste Montouris, Paris**

- University Medical Center **CHU Saint Etienne, Saint Etienne**
- University Medical Center **University Vita-Salute, Scientific Institute H. San Raffaele, Milano**
- Medical Center **Spire Washington Hospital , Tyne and Wear**
- University Medical Center **Nuffield Health - University Hospitals Bristol (UHB) - Bristol Royal Infirmary and Southmead Hospitals , Bristol**
- Medical Center **Blackpool Victoria Hospital , Blackpool**
- Medical Center **North-Estonian Medical Center Foundation , Tallinn**
- University Medical Center **Všeobecná fakultní nemocnice v Praze (VFN) a 1. - General University Hospital and First Faculty of Medicine Charles University , Praha**
- Medical Center **Urologická klinika - Fakultní nemocnice , Olomouc**
- University Medical Center **St. Marina University Hospital , Varna**
- Medical Center **Med.Landeskrankenhaus Vöcklabruck , Vöcklabruck**
- Medical Center **Hanuschkrankenhaus , Wien**
- University Medical Center **Moscow State University of Medicine and Dentistry named after A.I.Evdokimov , Moscow**
- University Medical Center **Vall d'Hebron University Hospital - Autonoma Universitat Barcelona , Barcelona**
- Doctor's Practice **Carouge**
- Medical Center **URO-TIP Urological Diagnosis Center , Istanbul-Suadiye**
- Medical Center **Acıbadem Kozyatağı Hospital , Istanbul**
- Medical Center **Krankenhaus der Barmherzigen Brüder, Wien**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/10/02**
- Target Sample Size: **391**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

- **Men at risk of PCa scheduled for first biopsy with serum total PSA**

**≤ 20 ng/ml (≤ 10 ng/mL if taking 5-alpha reductase inhibitors) from maximally 3 months ago**
**•Signed informed consent**

**Exclusion criteria**

- **Previous prostate biopsy**
- **Confirmed PCa**
- **PSA > 20 ng/ml (or > 10 ng/mL if taking 5-alpha reductase inhibitors)**
- **Active urinary tract infection**
- **Presence/history of any confirmed cancer**
- **Recent prostatic surgery (past 6 months)**
- **History of pelvic radiotherapy**

## Addresses

■ **Primary Sponsor**

**Advanced Medical Diagnostics SAWaterloo Office Park Bât i bte 3**
**Drève Richelle, 161**
**1410 WATERLOO**
**Belgium**

Telephone: **+32 (0)2 354 80 30**
Fax: **+32 (0)2 354 80 49**
E-mail: **clinical at histoscanning.com**
URL: **[---]***

■ **Contact for Scientific Queries**

**Cliniques Universitaires Saint-Luc Urology Department**
**Mr. Professor Bertrand TOMBAL**
**Avenue Hippocrate 10**
**1200 BRUSSELS**
**Belgium**

Telephone: **+32 2 7641415**
Fax: **+32 2 7649083**
E-mail: **bertrand.tombal at uclouvain.be**
URL: **[---]***

■ **Contact for Public Queries**

**Advanced Medical Diagnostics SA Waterloo Office Park Bât i bte 3**
**Ms. MSc Sophie Danloy**
**Drève Richelle, 161**
**1410 WATERLOO**
**Belgium**

**Contact for Public Queries**

**Advanced Medical Diagnostics SA Waterloo Office Park Bât i bte 3**
**Ms. MSc Sophie Danloy**
**Drève Richelle, 161**
**1410 WATERLOO**
**Belgium**

Telephone: **+32 (0)2 354 80 30**
Fax: **+32 (0)2 354 80 49**
E-mail: **clinical at histoscanning.com**
URL: **[---]***

## Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**Advanced Medical Diagnostics sa/nv**
**WOP, Bât.i, Bte3, Drève Richelle 161**
**1410 Waterloo**
**Belgium**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

## Trial Publications, Results and other documents

*Please note:*
*There are additional attributes available concerning this trial. To open an extended view please click here.*