PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Observational study of therapy with High Intensive Focused Ultrasound (HIFU) at Prostate Cancer

Trial Acronym

HIFU registry

URL of the trial

http:///

Brief Summary in Lay Language

Patients with prostate cancer are scheduled to receive high-intensity, focused ultrasound (HIFU) therapy. It is intended to ensure the most reliable statement possible regarding treatment success and therapy safety for future patients. For this it is necessary to record therapy data and results of follow-up of almost every HIFU therapy.
For this purpose, an Internet-based database was installed. This database documents the clinical and epidemiological data of the patients, the therapeutic parameters, patient stickers, the postoperative course in quality of life and the healing result. These data are pseudonymised after strict assignment to the personal data in the attending clinic and under strictest privacy concerns. They are identifiable only to the attending physician.
The database is managed centrally by IOMTech GmbH (Berlin). The database was subject to editions of privacy. For this reason, patients receive multiple questionnaires, twice in the first year, then once a year. In it, they are asked about the current PSA and any other therapies, as well as the quality of life. It is especially about the continence and the potency, as well as any problems with urination. The content of the questionnaire is entered electronically in the database, the paper version remains under the usual conditions of medical confidentiality in the patient record.

Brief Summary in Scientific Language

Prostate cancer, the most common male tumor disease in the Federal Republic of Germany, can be curatively treated via various therapeutic measures. High Intensity Focused Ultrasound (HIFU) has been used clinically for many years. The oncotherapeutic effectiveness and the side effect spectrum are in clinical studies well documented. However, data from larger series from the health services research is missing. In September 2009, new interdisciplinary quality S3 guidelines were published for the early detection, diagnosis and treatment of the various stages of prostate cancer. It states that currently no study data available, which allow an evaluation of HIFU. A routine use of the therapy for the indication is therefore not justified. The background text of this statement clarifies that HIFU

should, if possible, be carried out as part of clinical observations. Only one especially in the medium term, the high density of therapy data can justify a sufficient basis for a therapy recommendation with a better level of evidence. An Internet-based database for recording the required parameters already exists since 2009: the so-called "@-registry". In this database, the clinical and epidemiological data of the patients, the therapy parameters and the postoperative course in quality of life and oncotherapeutic outcome documented. With the application observation presented here, we strive for a comprehensive system for almost complete recording of all HIFU therapies in the Federal Republic of Germany.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00018103**
- Date of Registration in DRKS: **2019/09/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **13/13 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1239-3333**

Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **- Almost all in Germany with HIFU-treated patients should be included about 1000 patients**
  - All cases to be documented for the observation of the application are carried out with the devices of EDAP TMS (Vaulx-en-Velin, France).
  1. Baseline:
  If HIFU therapy is planned for a patient with prostate cancer, clarification of

the planned documentation of the patient's clinical data within the framework of the "@ registry". In the course of the following parameters are recorded and documented:
• Staging by assessing the local stage (T1 / T2 / T3), lymph node stage (N0 / NX / N1) and stage of metastasis (M0 / MX / M1).
• Medical comorbidity (including previous operations).
• Initial PSA value and, if known, additional PSA values in the course.
• The histologic findings with date. It is differentiated whether the tissue was obtained by biopsy, by transurethral resection or otherwise.
• Basic imaging: MRI / CT / PET scan / whole body scintigraphy / ultrasound / transrectal ultrasound.

2. Therapy Parameters of HIFU Therapy:
- Date of Therapy, Therapy Protocol, Intention of Therapy: Complete Gland, focal therapy (yes / no or nerve-sparing planned, if so: one-sided / bilateral), number of total administered Lesions, treated volume, duration of treatment, prostate volume (TRUS), prostate AP diameter, prostate length, prostate width, anesthesia form, pretreatment, in particular TUR-P / TUI-P / urethrotomy o. A. (if necessary, the number of grams of tissue obtained in the transurethral resection). Type of permanent catheter insertion (suprapubic / transurethral), date of catheter removal and total duration of catheterization.

3. Follow up:
There should be a follow-up at yearly intervals. For this purpose, dynamic progress sheets are created, which include a recurrence / progress by means of PSA history and documented control histology. Any imaging or clinical findings can be recorded. Furthermore, the follow-up includes standardized questionnaires regarding micturition problems, general quality of life, continence and potency, eventually Accompanying or sequelae, especially inpatient admissions, surgical therapy etc documented.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Overall survival of patients
There should be a follow-up at yearly intervals. For this purpose, dynamic progress sheets are created, which document a recurrence / progress by means of PSA course and possibly obtained control histology. Any imaging or clinical findings can be recorded.

Overall survival of patients
There should be a follow-up at yearly intervals. For this purpose, dynamic progress sheets are created, which document a recurrence / progress by means of PSA course and possibly obtained control histology. Any imaging or clinical findings can be recorded.

Secondary Outcome

- Tumor-specific survival
- Analysis of the acute and late toxicity of the procedure (effectiveness and effectiveness of HIFU therapy)
The follow-up includes standardized questionnaires regarding micturition problems, general quality of life, continence and potency, and finally, concomitant or sequelae, in particular hospitalisation, surgical therapy or others are documented.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Urologie und Kinderurologie, Magdeburg**
- Medical Center **Klinikum Fürth, Klinik für Urologie und Kinderurologie, Fürth**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/13**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

1. Patients with prostate cancer in whom a local therapy an improvement of disease situation promises
2. Consent to voluntary participation in the observational study after complete education on nature and purpose of observation, confirmed by signature on enlightenment document

Exclusion criteria

1. Acute, untreated urinary tract infection
2. Pre-existing urinary or rectal fistula
3. Anal stenosis, the introduction of the HIFU transducer does not allow

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

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

Trial Publications, Results and other documents

Additional Trial Attributes

- *Urological disease:* ***prostate cancer***
- *If other, please specify:* ***[---]****
- *Onset of therapy:* ***first-line***
- *If other, please specify:* ***[---]****
- *If other, please specify:* ***[---]****
- *Study recommendations:* ***trial sites in demand***
- *If other, please specify:* ***[---]****
- *German director of clinical investigation:*

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  URL: **[---]***

- *Function of contact:* ***[---]****
- *Non-interventional study:* ***Yes***
- *Stage:* ***localized***

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*