

The avatera registry for observing the avatera system in use for urological and gynaecological surgery across 10 European clinical centres

Submission date 10/06/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/02/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The avatera robotic system supports surgeons in “keyhole” minimally invasive surgery in urology and gynecology. The manufacturer of this system, avateramedical GmbH - Jena, Germany - is legally required to monitor the clinical application of this medical device in a post-market clinical follow-up. The clinical performance of the avatera system is observed and the observation is documented in order to ascertain its safe and efficient usage. This observation takes place in 10 clinical centres across Europe recording successful completion of the surgical intervention with the avatera system and recovery of 1000 patients. The avatera registry will collect and analyse all observations into one dataset. This overview will allow avateramedical to spot sufficiencies and deficiencies of the avatera system in order to establish and maintain a safe medical device.

Who can participate?

patients who are eligible for minimally invasive urological or gynecological surgery

What does the study involve?

Clinical centres participating in the avatera observation will ask patients who are eligible for minimally invasive urological or gynecological surgery at the surgeon’s discretion to consent to documentation and analysis of data related to the patient’s disease and recovery.

What are the possible benefits and risks of participating?

In combination with technical data of the avatera system, avateramedical will obtain important feedback on the safe and efficient performance of its avatera system.

Where is the study run from?

avateramedical GmbH (Germany)

When is the study starting and how long is it expected to run for?

January 2021 to September 2024

Who is funding the study?
avateramedical GmbH (Germany)

Who is the main contact?
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Contact information

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Scientific

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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

The avatera registry for the post-market clinical follow-up, non-interventional observation of using the avatera system in robot-assisted urological and gynaecological surgery across 10 European clinical centres

Study objectives

The avatera registry summarizes the non-interventional observation of the avatera system in routine clinical practice across 10 European clinical centres with no issue in research. The aim of this post-market clinical follow-up observation is to collect evidence of the safety and effectiveness of this surgical robotic system

Ethics approval required

Old ethics approval format

Ethics approval(s)

The avatera registry serves as a database collecting evidence from participating clinical centres. It therefore does not require ethics approval. The documentation of the observation in the clinical centres engaged is presented to the national local ethics committee in charge, respectively.

Study design

Prospective non-interventional observational multicentric registry

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Robot-assisted surgery with the avatera system in urology and gynaecology

Interventions

The source data of the intended registry is the observation of the clinical application of the Avatera robotic system. Patients who agreed to participate in the observation will be accompanied by documentation from their admission visit to their release visit and 30- and 90-day postoperative telephone interviews, to document and describe:

1. Their diagnoses to be treated minimally invasive
2. Their health status (ASA scores, pain assessment score, activity score)
3. Successful surgery with the Avatera system or necessity to interrupt/abort/convert to another surgical method
4. Any surgical or technical complications

Intervention Type

Procedure/Surgery

Primary outcome(s)

Conversion rate of the robot-assisted surgery to an alternative surgical method on the day of surgery, calculated as the number of patients who required conversion to an alternative surgical method (manual laparoscopic or open surgery) under surgery divided by the number of all patients who underwent surgery. The basis for the calculation is the total population.

Key secondary outcome(s)

1. Perioperative complications: the frequencies of the observed complication categories are presented per visit resp. interview and sorted by descending frequency on the day of surgery, daily postoperative visit until release visit, postoperative interview on day 30 and day 90
2. Perioperative process times measured using timetracking by any clock in the operating theatre at preparation time of the system, docking, cut-to-suture time, console time and undocking
3. Estimated intraoperative blood loss measured by estimation of suction liquid volume minus any rinsing volume at postoperative
4. Intraoperative blood transfusions, including their number, counted at postoperative
5. Duration of the inpatient stay, measured as the period from the day of admission until the day of release, at the release visit
6. Patient-related outcomes: pain assessment and activity status measured using interview and patient's assessment on the Verbal Rating Scale and the ECOG/WHO activity score at the admission visit, daily postoperative visit until release visit, and postoperative interview on day 30 and day 90

Completion date

30/09/2024

Eligibility

Key inclusion criteria

Patients eligible for minimally invasive surgery in urology or gynaecology

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients not eligible for minimally invasive surgery in urology or gynecology

Date of first enrolment

01/06/2022

Date of final enrolment

01/12/2023

Locations

Countries of recruitment

Germany

Greece

Hungary

Study participating centre

University Hospital of Patras

Urology Department

26504 Pto

Patras

Greece

26504

Study participating centre

Vinzenzkrankenhaus Hannover GmbH

Department of Urology

Lange-Feld-Straße 31

Hannover

Germany

30559

Study participating centre

Universitätsklinikum Schleswig-Holstein

Department of Gynecology

Ratzeburger Allee 160

Lübeck

Germany

23562

Study participating centre

Jahn Ferenc Dél-Pest Hospital

Department of Urology

Köves u. 1

Budapest

Hungary

1204

Sponsor information

Organisation

avateramedical GmbH

Funder(s)

Funder type

Industry

Funder Name

avateramedical GmbH

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be stored in a non-publicly available repository. The data repository is a database provided by the Clinical Research Organization GWT-TUD GmbH, Dresden, Germany. The database is run by the system secuTrial, hosted by interactiveSystems (iAS), Berlin, Germany. Data management is solely owned by the CRO. All participants of the avatera PMCF-observation have been informed of the purpose of this observational investigation and succeeding summary of all participating centres in a registry. Participants could only be included after written consent, which explicitly covers the allowance to use pseudonymised person-related data.

IPD sharing plan summary

Stored in non-publicly available repository