ISRCTN45854742 https://doi.org/10.1186/ISRCTN45854742

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

Registration date
28/07/2022

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr Elke Grunow
ava-PMCF-registry@avateramedical.com

Contact information

Type(s)
Scientific

Contact name
Dr Elke Grunow

Contact details
avateramedical GmbH
Ernst-Ruska-Ring 23
Jena
Germany
07745
+49 (0)3641 2724 163
ava-PMCF-registry@avateramedical.com

Type(s)
Scientific

Contact name
Ms Katja Herrmann

Contact details
avateramedical GmbH
Ernst-Ruska-Ring 23
Jena
Germany
07745
+49 (0)151 72433145
ava-PMCF-registry@avateramedical.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Registry

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
11/01/2021

Completion date
30/09/2024

Eligibility

Key inclusion criteria
Patients eligible for minimally invasive surgery in urology or gynaecology

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 patients per clinical centre

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 Pio
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

Sponsor details
Ernst-Ruska-Ring 23
Germany
Jena
Germany
07745
+49 (0)3641 2724 0
info@avateramedical.com

Sponsor type
Industry

Website
https://www.avatera.eu/home

Funder(s)

Funder type
Industry

Funder Name
avateramedical GmbH

Results and Publications

Publication and dissemination plan
The avatera registry discloses the observation, documentation and summary of the avatera system post-market clinical follow-up. It is the aim and wish of participating investigators and the sponsor to share experiences with the interested public and scientific auditory.

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be stored in a non-publically 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