ISRCTN14196575 https://doi.org/10.1186/ISRCTN14196575

Robotic and laparoscopic procedures in the urological field

Submission date 04/07/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/07/2026	**Overall study status** Ongoing	
Last Edited 06/07/2026	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Comparison between robotic and laparoscopic approach to treat urological diseases

Study objectives
To assess the best options to treat urological conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/11/2019, UNIBUC EC (9 Panduri st., Bucarest, 54367, Romania; +40 0752011828; office@g.unibuc.ro), ref: RO st 3345/2020

Primary study design
Observational

Secondary study design
Case-control study

Study type(s)

Health condition(s) or problem(s) studied
Benign and neoplastic urological condition

Interventions
This observational study enrols patients before undergoing a surgical procedure and follows them prospectively for 5 years after surgery. As the final disease classification and risk stratification depend on the postoperative histopathology report, which is not available at enrolment, no randomization is performed. Patients are monitored according to standard clinical practice and European Association of Urology (EAU) follow-up guidelines, with surveillance schedules tailored to the histopathological findings. Clinical, pathological, and outcome data are collected and analysed using appropriate statistical methods to evaluate long-term patient outcomes and associations with disease characteristics. The results will provide evidence on prognosis and management in routine clinical practice. The follow-up approach and the fact that histopathology results are unknown at enrolment are clearly explained in the consent documentation.

Intervention Type
Other

Primary outcome(s)
1. Disease-free survival (DFS) measured using data collected from patient medical records at baseline and 5 years follow up

2. Duration of the procedure measured using data collected from patient medical records at baseline and 5 years follow up

3. Neoplastic-related relapse measured using data collected from patient medical records at baseline and 5 years follow up

4. Bleeding during the procedure measured using data collected from patient medical records at baseline and 5 years follow up

5. Cost of the procedure measured using data collected from patient medical records at baseline and 5 years follow up

Key secondary outcome(s)

Completion date
31/12/2030

Eligibility

Key inclusion criteria
Patients who underwent robotic and laparoscopic procedures for urological conditions

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
500

Key exclusion criteria
1. Locally advanced or metastatic disease
2. Benign lesion at histopathology
3. Multiple renal masses
4. Coagulopathy or anticoagulants that could not be stopped
5. End-stage renal disease
6. Pregnancy

Date of first enrolment
01/07/2026

Date of final enrolment
31/12/2030

Locations

Countries of recruitment
France

Greece

Italy

Romania

Russian Federation

Spain

Sponsor information

Organisation
Regione Lombardia

ROR
https://ror.org/020dw9k11

Funder(s)

Funder type

Funder Name
Regione Lombardia

Alternative Name(s)
Lombardy Region, Region of Lombardy

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Funder Name
Foundazione ROUTE

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available