ISRCTN55335030 https://doi.org/10.1186/ISRCTN55335030

The influence of inflammation on surgery of the male and female urinary tract system and male reproductive organs

Submission date 23/02/2022	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/03/2022	**Overall study status** Ongoing	
Last Edited 01/04/2022	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Inflammation (the body's response to cell damage) plays a critical role in many chronic diseases. In particular, in patients with cancer, it has been shown that the presence of a chronic inflammation status is involved in the development and progression of the tumour. For example, in urology, patients with chronic prostatic inflammation are at higher risk of urinary symptoms, urinary retention and need for prostate surgery.

The gold standard for the diagnosis of tissue inflammation is the examination of a tissue sample, which cannot always be performed for both ethical and procedural issues. For this reason, a lot of studies have tried to identify a blood test for inflammation. In recent years, many authors have highlighted some simple blood laboratory tests (such as blood cell count, albumin, count of platelet, fibrinogen, C reactive protein etc) that seem to help clinicians in the identification of patients at higher risk of complications and unfavourable outcomes after surgery.

The role of these inflammatory markers in the urological field is still unclear.

The design of the "IRU Study" expects to prospectively collect all the laboratory tests required in the preoperative evaluation phase of patients undergoing urological surgery procedures, in order to calculate the main inflammatory indexes and to look for the association of these with post-surgical outcomes.

Who can participate?
Patients older than 18 years undergoing urological surgery procedures.

What does the study involve?
A prospective survey of patients undergoing urological surgery procedures.
Patients will undergo the following clinical/instrumental assessments at baseline and at postoperative assessments:
• Historical and physical examination
• Blood sample

• Urine examination with urine culture and possible antibiogram
• Preoperative staging examinations for patients with cancer
• Preoperative routine diagnostic tests for benign diseases
• Intraoperative evaluation
• Histopathological analysis
Follow up for up to 5 years.

What are the possible benefits and risks of participating?
None

Where is the study run from?
European Urological Center (Italy)

Where is the study starting and how long is it expected to run for?
February 2021 to October 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Luca Cindolo, lucacindolo@virgilio.it

Contact information

Type(s)
Scientific

Contact name
Dr Luca Cindolo

ORCID ID
http://orcid.org/0000-0002-0712-2719

Contact details
Via Anelli 82
Vasto
Italy
66054
+39 3476975340
lucacindolo@virgilio.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The role of inflammation in urological surgery

Acronym
IRU STUDY

Study objectives
Inflammation plays a critical role in many chronic diseases. In the urological field, patients with chronic prostatic inflammation are at higher risk of severe voiding symptoms, acute urinary retention and prostate surgery. Blood laboratory tests, such as blood cell count, albumin, PLT, fibrinogen, CPR and PCT, seem to play a role in the identification of patients at higher risk of complications after surgical procedures.
The aim of this study is to calculate the main inflammatory indexes for patients undergoing benign and malignant urological surgery in order to evaluate their association with post-surgical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/09/2021, Ethical Committee of Nord Area of Emilia Romagna Italian Health Care System (Via del Pozzo, 71 – 41124 Modena, Italy; +39 59-4224472; comitato.etico@pec.aou.mo.it), ref: 0026972/21

Study design
Observational prospective longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files (in Italian)

Health condition(s) or problem(s) studied
Urological surgery procedures

Interventions
According to EAU guidelines and pre-hospitalization protocols, all eligible patients will undergo the following clinical/instrumental assessments:
• Historical and physical examination
• Blood sample
• Urine examination with urine culture and possible antibiogram
• Preoperative staging examinations for patients with cancer
• Preoperative routine diagnostic tests for benign diseases
• Intraoperative evaluation
• Histopathological analysis

Follow-up assessments will be performed according to the diagnosis and different kinds of surgical procedures.
The duration of the study is 5 years

Intervention Type
Other

Primary outcome measure
Inflammation indexes will be calculated by the neutrophils/lymphocytes, neutrophils /monocytes, lymphocytes/platelets, CPR, PCT, Albumin, fibrinogen, modified Glasgow prognostic score (mGPS) measured at the time of surgery and at post-operative evaluations using blood and urine samples

Secondary outcome measures
Obtained by review of medical records at baseline and at follow up appointments:
1. Lifestyles, physical activity and metabolic syndrome measured using: smoker status, BMI, hypertension, diabetes, dyslipdemia, COPD, ECOG, NYHA.
2. Frailty index measured using; questionnaire G8; sFI calculated including the precence of diabetes, functional status of patient before surgery, COPD, heart failure, hypertension; Charlson Comorbidity index.
3. Disease progression, disease-free survival, in patients with cancer of the urogenital system
4. measured using: overall survival (months) and recurrence free survival (months)
5. Histological characteristics of urogenital cancers measured using histopathological reports.
6. Histological inflammation measured using histopathological reports.
7. Main urodynamic parameters in patients undergoing benign prostatic obstruction surgery
8. measured using Uroflowmetry maximum urinary flow (Qmax), voided volume and post void residual
9. Functional recovery after urological surgery (assessed as sexual activity, ejaculation disorders, infertility and urinary incontinence) measured using IPSS, PUF, NIH-CPSI, IIEF questionnaires.

Overall study start date
09/02/2021

Completion date
08/10/2026

Eligibility

Key inclusion criteria

Patients older than 18 undergoing the following urological surgery procedures:
1. Radical caste Tommy
2. Surgery for benign prostatic obstruction
3. Radical and partial nephrectomy
4. Radical nephroureterectomy
5. Radical prostatectomy
6. Ureterolithotripsy
7. Orchifunicolectomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
Patients who, due to age or clinical condition, are unable to receive the information and to sign the informed consent

Date of first enrolment
08/10/2021

Date of final enrolment
08/09/2026

Locations

Countries of recruitment
Italy

Study participating centre
Hesperial Hospital
Via Arquà, 80/A
Modena
Italy
41125

Sponsor information

Organisation
European Urological Center C.Ur.E SRL/STP

Sponsor details
Viale Corassori, 72
Modena
Italy
41124
+39 3316125203
amministrazione@centrourologico.it

Sponsor type
Hospital/treatment centre

Website
https://www.centrourologico.it/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The preliminary and final results of the study will be collected and processed by the coordinating center which will be responsible for the preparation of scientific papers for publications after prior internal discussion. Peer reviewed indexed journals will be the main journal target. Oral presentations at national and/or international urological congresses will be also planned and realised.

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. lucacindolo@virgilio.it

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	09/02/2021	03/03/2022	No	Yes