

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

<b>Submission date</b> 23/02/2022	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/03/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/04/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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](mailto:lucacindolo@virgilio.it)

## Contact information

### Type(s)

Scientific

### Contact name

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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 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

### Study type(s)

Other

### 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(s)**

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

## **Key secondary outcome(s))**

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.

## **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. Orchifuniclectomy

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

### 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](mailto:lucacindolo@virgilio.it)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 1	09/02/2021	03/03/2022	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes