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Clinical outcomes for patients diagnosed with renal cancer and caval thrombus involvement considering surgery

Submission date
09/01/2025

Recruitment status
Recruiting

Registration date
07/07/2025

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
There is considerable uncertainty on how best to treat and select the patients for this high-risk surgery. Surprisingly, the current UK surgical practice of this operation is largely unknown. This lack of knowledge creates a challenge in providing information and optimal care to patients. This study is the UK's first multicentre prospective surgical registry dedicated to improving the care of patients with kidney cancer with caval extension. The researchers will collect detailed information on patients' pre- and post-operative journey, understanding the impact of their surgery and seek information on contemporary surgical practice across the country. In addition, the researchers will collate real-world risks associated with surgery. After 18 months they will hold a national meeting using their results and others in the field using a validated consensus methodology to generate a set of clinical recommendations and create a standard operating procedure for this form of surgery. This will help to provide contemporary informed risks and benefits to patients and places improving patient care from high-risk surgery at the core of the project. Finally, the researchers will generate a patient information leaflet for this form of surgery which they hope can be adopted nationally (e.g. British Association of Urological Surgeons).

Who can participate?
Any person over the age of 18 referred to a specialist cancer meeting in a hospital that is involved in the study and has a new diagnosis of suspected renal cancer with a tumour clot (caval thrombus) involvement

What does the study involve?
Patients will undergo routine NHS care and data will be collected from their routine NHS visits.

What are the possible benefits and risks of participating?
There are no additional visits or requirements from the patient above that of routine practice. No changes in patient care result from this study that is observing current practice. No material risk exists to the patient.

Where is the study run from?
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2024 to January 2027

Who is funding the study?
The Urology Foundation (TUF) (UK)

Who is the main contact?
Mr Martin Connor, m.connor@imperial.ac.uk

Contact information

Type(s)
Public, Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
No 1057, Imperial College Healthcare NHS Trust

Study information

Scientific Title
Clinical outcomes for CAVAL THROMbus involved Renal Cell Cancer (Imperial Renal 1 – CAVALThromb): a prospective, multicentre registry

Acronym
IR1-CAVALThromb

Study objectives
The project is aimed to improve our knowledge and understanding of the optimal surgical treatment for patients with renal cell carcinoma with inferior vena cava involvement

Ethics approval required
Ethics approval not required

Ethics approval(s)
As an evaluation of current surgical practice, requirements for formal ethics committee approval were waived by the UK NHS Health Research Authority patients. The registry will be implemented and reported in accordance with the ethical principles of the Declaration of Helsinki. IR1-CAVALThomb will be registered at each side using the current NHS service evaluation forms with associated reference numbers prior to commencing work.

Study design
Multicenter registry study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Quality of life, Treatment, Safety, Efficacy

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
Renal cell carcinoma with inferior vena cava thrombus involvement

Interventions
IR1-CAVALThromb is a prospective, multicenter, registry study. The researchers plan to invite several centers to the register. They will collect data on patients who undergo radical nephrectomy with caval thrombectomy and non-surgical treatments for their advanced renal cancer.

Broadly the researchers will look at:
1. Patient-reported and baseline clinical outcomes
2. Intraoperative outcomes
3. Adverse events recorded using the Clavien-Dindo classification
4. Oncological outcomes

Intervention Type
Procedure/Surgery

Primary outcome measure
Standard operating procedure (SOP) for radical nephrectomy and caval thrombectomy surgery generated using the RAND/University of California at Los Angeles (UCLA) appropriateness method, completed once the last patient recruited has reached 3-month follow-up

Secondary outcome measures
1. Morbidity of patients undergoing surgery and those who do not undergo immediate operative management assessed using the Clavien-Dindo Classification and/or the common terminology criteria for adverse events (CTCAEv5.0) at 3-month follow-up
2. Patient-reported outcome measures and health-reported quality-of-life measured using:
2.1. Clinical frailty score at baseline and 3-month follow-up
2.2. EORTC QLQ-F17 and EQ-5D-5L validated questionnaire at baseline and 3-month follow-up
3. Surgical complications assessed using the Clavien-Dindo Classification of patients at 3 months follow-up
4. Key recommendations for optimal patient care and objectives for further research developed using the RAND/University of California at Los Angeles (UCLA) appropriateness method, completed once the last patient recruited has reached 3-month follow-up

Overall study start date
01/09/2024

Completion date
20/01/2027

Eligibility

Key inclusion criteria
Any person over the age of 18 years referred to a supra-regional MDT following a new diagnosis of suspected caval thrombus involved renal cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Age under 18 years old
2. Patients who are found to have no evidence of caval thrombus on dedicated tertiary imaging

Date of first enrolment
20/01/2025

Date of final enrolment
20/01/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
The Royal Marsden Hospital (london)
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
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NR4 7UY

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.uk/

ROR
https://ror.org/056ffv270

Funder(s)

Funder type

Charity

Funder Name
Urology Foundation

Alternative Name(s)
TUF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in a peer-reviewed journal
2. Presentation at uro-oncology conferences in the United Kingdom and internationally.

Intention to publish date
20/01/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the small number of patients and the risk of identifiable data

IPD sharing plan summary
Not expected to be made available