ISRCTN61007118 https://doi.org/10.1186/ISRCTN61007118

THERApy de-escalation for TESTicular cancer

Submission date 22/02/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/02/2024	**Overall study status** Ongoing	
Last Edited 12/08/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
THERATEST is looking to collect data from patients with testicular cancer actively receiving de-escalation treatments or other standard-of-care treatments in two UK hospitals. THERATEST is a feasibility study to determine whether patients are willing to be recruited, the impact of de-escalation treatments on patients' cancers and quality of life, whether a larger study should proceed with these treatments, and if so how the study should be conducted. A feasibility study prepares the ground for a larger study, improves the chances of the subsequent study producing valuable evidence, and helps to avoid wasting precious resources on larger trials that are unlikely to be informative. THERATEST aims to bridge the current knowledge gap and allow clinicians to design bigger trials to actively compare the different treatment strategies.

Who can participate?
Patients with testicular cancer aged from 16 to 100 years old

What does the study involve?
Eligible participants will receive one of two possible treatment strategies:

De-escalation treatment with Carboplatin AUC 10 at 21-day intervals. Each 21-day interval is called a cycle. Carboplatin is administered by injecting it into a vein through a cannula over approximately 60 minutes in a hospital. Three cycles of this treatment will be given.

OR

Other types of standard-of-care treatments such as combination chemotherapy (e.g. bleomycin, etoposide and platinum (BEP) or etoposide and platinum (EP)) or radiotherapy. These will be offered to participants if they do not wish to receive Carboplatin AUC10 or if their doctor believes this is not the best treatment option for them. The details of the duration and frequency of these treatments will be given to them by your doctor.

After completing the treatment, participants will be followed for 2 years. This will allow the collection of data on long-term side effects, how well the treatment controlled the growth of the cancer as well as the impact it had on quality of life. All visits will be in line with standard-of-care visits and they will not have to attend additional hospital visits.

What are the possible benefits and risks of participating?
This trial aims to find out information that may help people with testicular cancer. The treatments participants will receive are the same as standard-of-care treatments. There is no additional benefit over and above the standard of care.

Where is the study run from?
Queen Mary University of London (Queen Mary) is the Sponsor for this study and it is based in the United Kingdom.

When is the study starting and how long is it expected to run for?
May 2023 to May 2028

Who is funding the study?
Barts Charity

Who is the main contact?
bci-theratest@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Prabhakar Rajan

Contact details
Queen Mary University of London, Charterhouse Square
London
United Kingdom
EC1M 6BQ
020 7882 8487
bci-theratest@qmul.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
305109

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 305109, CPMS 59883

Study information

Scientific Title
THERApy de-escalation for TESTicular cancer

Acronym
THERATEST

Study objectives
THERATEST is a feasibility study to determine whether patients are willing to be recruited, the impact of de-escalation treatments on patients' cancers and quality of life, whether a larger study should proceed with these treatments, and if so how the study should be conducted. A feasibility study prepares the ground for a larger study, improves the chances of the subsequent study producing valuable evidence, and helps to avoid wasting precious resources on larger trials that are unlikely to be informative. It is hoped that information from THERATEST will bridge the current knowledge gap and allow clinicians to design bigger trials to actively compare the different treatment strategies.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/01/2024, REC London Riverside (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8243; riverside.rec@hra.nhs.uk), ref: 23/LO/0972

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Patients with testicular seminoma who are negative/low for tumour markers and unifocal ipsilateral Stage IIA or <3 cm IIB will be assessed for robot-assisted retroperitoneal lymph node dissection (rRPLND)

Interventions
THERATEST is an observational cohort study of patients receiving standard-of-care (SOC) treatments (combination chemotherapy or radiotherapy) or de-escalated treatments (primary rRPLND or Carboplatin AUC10) for stage II seminoma.

A. rRPLND cohort: Patients with seminoma who are negative/low for tumour markers and unifocal ipsilateral Stage IIA or <3cm IIB will be assessed for rRPLND. Patients who are eligible for rRPLND will undergo surgery followed by adjuvant treatment or surveillance as determined by their clinical teams based on post-operative histology as per SOC. Patients who are not deemed eligible for or decline rRPLND will be offered either BEP/EP chemotherapy or radiotherapy with or without neoadjuvant Carboplatin AUC7 and will continue to be followed in the study.

B. Carboplatin AUC10 cohort: Patients with stage II seminoma will be offered Carboplatin AUC10. Those deemed ineligible for Carboplatin AUC10 or who decline this treatment option will be offered either BEP/EP chemotherapy or radiotherapy and will continue to be followed in the study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility will be measured using recruitment and retention (number of participants recruited per month and retained annually) data collected from the patient visits and recorded within the study electronic database at one time point

Key secondary outcome(s))
1. Health-related quality of life measured using the change in domain scale scores/single item scores in European Organisation for Research and Treatment of Cancer (EORTC) QLQ-TC26 and EORTC QLQ-C30 before and after treatment(s)
2. Sexual drive, function, and overall satisfaction measured using the change in domain scale scores/single item scores in Brief Male Sexual Function Inventory (BMSFI), QLQ-TC26, and supplementary questions on retrograde ejaculation before and after treatment(s)
3. Progression-free survival (PFS) and overall survival (OS) rates to ensure these fall in line with standard-of-care treatment outcomes (>95%) [PFS rate at 2 years, defined as the proportion of patients who did not experience disease progression or death from any cause during the 2-year follow-up period. OS rate at 2 years, defined as the proportion of patients who did not experience death from any cause during the 2-year follow-up period.]
4. Safety and complications of all treatments measured using the incidence, nature and severity of adverse events with severity determined according to CTCAE v5.0 collected from consent until 6 weeks post-surgery or chemotherapy. Surgical complications will be assessed by the Clavien-Dindo scoring system, and analysing details of surgical complications, blood transfusion, ITU admission and dialysis rates from patient records up to 6 months post-rRPLND.

Completion date
31/05/2028

Eligibility

Key inclusion criteria
Each patient must meet all of the following inclusion criteria to be enrolled in the study:
1. Willing and able to provide written informed consent
2. Male
3. Age ≥16 years
4. Histologically confirmed seminoma (biopsy/orchidectomy)
5. Clinical stage II (standard of care cross-sectional imaging)
6. Ability to comply with the protocol, including but not limited to, completion of the patient-reported outcome questionnaires. rRPLND cohort-specific inclusion criteria

Participants must meet the following additional inclusion criteria to register for the rRPLND cohort:
1. Stage IIA and <3 cm IIB with unifocal ipsilateral lymph node within rRPLND template.
2. Negative or mildly elevated serum tumour markers, defined as:

2.1. AFP (alpha-fetoprotein) <10 ng/ml and non-rising on serial testing
2.2. BhCG (human chorionic gonadotropin) <50 mg/ml
2.3. LDH (lactate dehydrogenase) <1.5x upper limit normal
3. Fit for surgery, defined as meeting all of the following criteria:
3.1. Body mass index (BMI) <34
3.2. Charlson comorbidity index ≤3
3.3. ECOG Performance status 0-1
3.4. No significant cardio-pulmonary disease, or other uncontrolled intercurrent illness that would limit fitness for surgery in the opinion of the investigator
3.5. No previous open intra-abdominal surgery Carboplatin AUC10 cohort-specific inclusion criteria

Participants must meet the following additional inclusion criteria to register for the Carboplatin AUC10 group:
1. Serum tumour markers, defined by IGCCCG "good risk" criteria:
1.1. AFP <10 ng/ml
1.2. any BhCG
1.3. LDH <2.5x ULN
2. Glomerular filtration rate by EDTA clearance over 25 ml/min (a measured creatinine clearance using Cockcroft and Gault would be allowed if unable to perform EDTA clearance)
3. ECOG Performance status 0-2
4. Patients must be sterile or agree to use adequate contraception during the period of therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
Male

Key exclusion criteria
A patient will not be eligible for inclusion in this study if any of the following criteria apply:
1. Raised AFP > 10ng/ml that does not fall to <10ng/ml following orchidectomy
2. Previous chemotherapy or radiotherapy for the disease under study.
3. Previous or concurrent malignancy other than testicular cancer, unless treated with curative intent and with no known active disease present for ≥2 years before enrolment and felt to be at low risk for recurrence by the treating physician (for example: non-melanoma skin cancer or lentigo maligna; breast ductal carcinoma in situ; prostatic intraepithelial neoplasia; urothelial papillary non-invasive carcinoma or urothelial carcinoma in situ).
4. Any condition that, in the opinion of the investigator, would interfere with the evaluation of

study intervention or interpretation of patient safety or study results such as medical comorbidities impacting on QoL or medical conditions or other disorders that would affect adherence to study requirements.

Date of first enrolment
12/08/2024

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Royal Marsden Hospital
Royal Marsden Hospital
Downs Road
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Barts Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All study data shall be the property of Queen Mary University of London.
THERATEST Protocol v2.0 12 Dec 2023 Page 48 of 50
In the event that research misconduct or data integrity concerns have been raised, the sponsor, with senior management of the affected organisation in discussion with the CI, reserves the right to review, request a hold on publication submission or to refuse permission to publish. Responsibility for ensuring the accuracy of any publication from this study is delegated to the CI.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/07/2025	04/08/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes