

Trial of Imaging and Schedule in Seminoma Testis

Submission date 04/07/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 29/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/03/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-find-the-best-way-of-using-scans-to-monitor-men-after-treatment-for-seminoma-testicular-cancer>

Contact information

Type(s)

Scientific

Contact name

Dr Dipa Noor

Contact details

MRC Clinical Trials Unit at UCL
Institute of Clinical Trials & Methodology
90 High Holborn 2nd Floor
London
United Kingdom
WC1V 6LJ
+44 (0)20 7670-4747
mrcctu.trisst@ucl.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00589537

Protocol serial number

MRC TE24

Study information

Scientific Title

Trial of Imaging and Schedule in Seminoma Testis

Acronym

TRISST

Study objectives

To assess whether a reduced computed tomography (CT) schedule or magnetic resonance imaging (MRI) could be used as a safe and effective alternative to standard CT-based surveillance in the management of stage one seminoma testis patients without evidence of nonseminomatous germ cell tumour (NSGCT) elements.

As of 21/03/2012, the following amendments have been made to the record.
Australia, Canada and New Zealand have been removed from the countries of recruitment.
Anticipated end date has been modified from 01/11/2016 to 31/05/2020.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (East) Research Ethics Committee, 26/10/2007, ref: 07/H1306/127

Primary study design

Interventional

Study design

Open randomised phase III multicentre trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Seminoma testis

Interventions

1. Standard surveillance: CT-based, scans at 6, 12, 18, 24, 36, 48 and 60 months
2. CT-based surveillance: reduced schedule: scans at 6, 18, and 36 months
3. MRI-based surveillance: scans at 6, 12, 18, 24, 36, 48 and 60 months
4. MRI-based surveillance: reduced schedule: scans at 6, 18, and 36 months

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Proportion of patients relapsing with Royal Marsden Hospital (RMH) stage IIC or greater disease.

Primary and secondary outcome timepoint measurements will depend partly on recruitment and event rates. Recruitment will be for five years, and final analyses are expected to be nine years after the first patient is randomised. In addition, annual interim analyses will be performed with an independent data monitoring committee.

Key secondary outcome(s)

Current secondary outcome measure(s) as of 21/03/2012:

1. Mean abdominal mass size at relapse between CT and MRI
2. Time on surveillance before detection of relapse
3. First modality to detect relapse (patient symptom, clinical examination, tumour marker, chest X-ray [CXR], cross sectional image)
4. Extent of relapse according to International Germ Cell Cancer Collaborative Group (IGCCCG) classification (IGCCCG, 1997)
5. Disease free and overall survival according to schedule randomisation and prognostic grouping
6. Prospective evaluation of prognostic factors for relapse of stage I seminoma patients
7. Number of false positive MRIs
8. Resource use and costs

Primary and secondary outcome timepoint measurements will depend partly on recruitment and event rates. Recruitment will be for five years, and final analyses are expected to be nine years after the first patient is randomised. In addition, annual interim analyses will be performed with an independent data monitoring committee.

Previous secondary outcome measure(s):

1. Mean abdominal mass size at relapse between CT and MRI
2. Time on surveillance before detection of relapse
3. First modality to detect relapse (patient symptom, clinical examination, tumour marker, chest X-ray [CXR], cross sectional image)
4. Extent of relapse according to International Germ Cell Cancer Collaborative Group (IGCCCG) classification (IGCCCG, 1997)
5. Disease free and overall survival according to schedule randomisation and prognostic grouping
6. Prospective evaluation of prognostic factors for relapse of stage I seminoma patients

Primary and secondary outcome timepoint measurements will depend partly on recruitment and event rates. Recruitment will be for five years, and final analyses are expected to be nine years after the first patient is randomised. In addition, annual interim analyses will be performed with an independent data monitoring committee.

Completion date

29/09/2020

Eligibility

Key inclusion criteria

Current inclusion criteria as of 31/03/2011:

1. Histologically proven seminoma of the testis without evidence of NSGCT elements
2. Clinical stage I on the basis of clinical examination and CT scan of the chest, abdomen and pelvis. This CT scan should have been performed no more than 8 weeks before randomisation
3. No planned adjuvant therapy
4. Normal serum alphafetoprotein (AFP) post-orchidectomy and not known to be raised pre-

orchidectomy

5. Normal serum beta-human chorionic gonadotropin (β -HCG) at randomisation (may have been raised pre-orchidectomy)
6. Patient written, informed consent
7. Patients must be able to attend for regular surveillance
8. The interval between orchidectomy and randomisation should not normally exceed 8 weeks (although up to 10 weeks is acceptable in exceptional circumstances following discussion with the trial team)
9. Patients must be at least 16 years old

Previous inclusion criteria:

1. Histologically proven seminoma of the testis without evidence of NSGCT elements
2. Clinical stage one on the basis of clinical examination and CT scan of the chest, abdomen and pelvis
3. No planned adjuvant therapy
4. Normal serum alphafetoprotein (AFP) pre-orchidectomy and at randomisation
5. Normal serum beta-human chorionic gonadotropin (β -HCG) at randomisation (may have been raised pre-orchidectomy)
6. Patient written, informed consent
7. Patient must be able to attend for regular surveillance
8. The interval between orchidectomy and registration should not exceed eight weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

669

Key exclusion criteria

Current exclusion criteria as of 31/03/2011:

1. Co-existent or previously treated malignancy within 10 years, with the only exceptions being (i) successfully treated non-melanoma skin cancer or, (ii) RMH stage I germ cell tumour of the contralateral testis diagnosed more than 5 years earlier and managed by surveillance
2. Inability for any reason to comply with the trial investigations or follow-up schedules
3. Any contra-indication to MRI, for example, ferrous metal implants of any type, cardiac pacemaker or defibrillators, or history of injury by metal fragments
4. Spermatocytic seminomas

Previous exclusion criteria:

1. Co-existent or previously treated malignancy within ten years other than successfully treated non-melanoma skin cancer
2. Inability for any reason to comply with the trial investigations or follow-up schedules

3. Any contra-indication to magnetic resonance imaging, for example ferrous metal implants of any type, cardiac pacemaker or defibrillators, or history of injury by metal fragments

Date of first enrolment

01/11/2007

Date of final enrolment

31/07/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Huddersfield Royal Infirmary

West Yorkshire

United Kingdom

HD3 3EA

Study participating centre

35 other centres

United Kingdom

-

Sponsor information

Organisation

Medical Research Council (UK)

ROR

<https://ror.org/03x94j517>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C17084/A8690)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The trial data are held at MRC Clinical Trials Unit at UCL which encourages optimal use of data by employing a controlled access approach to data sharing. Requests for data can be made via application to the Trial Steering Committee. Further information on both the approach and the application process can be found here: http://www.ctu.mrc.ac.uk/our_research/datasharing/

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	management practices	17/03/2022	21/03/2022	Yes	No
Other publications		01/02/2012		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes