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Trial of Imaging and Schedule in Seminoma Testis

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

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

Study website
http://www.ctu.mrc.ac.uk/our_research/research_areas/cancer/studies/trisst_mrc_te24/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00589537

Secondary identifying numbers
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

Study design
Open randomised phase III multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
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.

Secondary outcome measures
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
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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.

Overall study start date
01/11/2007

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

Age group
Adult

Sex
Male

Target number of participants
660

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
England

United Kingdom

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)

Sponsor details
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Sponsor type
Research council

Website
http://www.mrc.ac.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Results from the primary analysis and pre-specified secondary analyses will be presented at relevant national/international meetings and will be published in peer-reviewed journals following funder open access requirements. A plain English summary of the results will be distributed to participants and will also be published on the study and funder websites.

Intention to publish date

01/10/2021

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?
Plain English results				No	Yes
Other publications	management practices	01/02/2012		Yes	No
Results article		17/03/2022	21/03/2022	Yes	No