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A randomised comparison of single agent carboplatin with radiotherapy for stage I seminoma of the testis following orchidectomy

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 07/07/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003014

Secondary identifying numbers
TE19

Study information

Scientific Title

Study objectives
1. To determine whether relapse rates are equivalent in patients with Stage 1 seminoma testis treated with either adjuvant radiotherapy or with single agent carboplatin at a dose of AUC 7 [7 x (GFR + 25)]
2. To document symptoms and aspects of quality of life before and after treatment, and to compare the acute and intermediate (1-2 year) side-effects of treatment using a diary card and EORTC QLQ-C30 together with a developmental testicular tumour questionnaire
3. To collect data on the incidence of late side-effects of treatment (such as bowel dysfunction) and second malignancies (the latter in parallel with an ongoing retrospective study of 2nd malignancies in such patients)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Testicular cancer

Interventions
1. One group receives radiotherapy following orchidectomy
2. The other group receives single agent carboplatin

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Carboplatin

Primary outcome measure
Time to relapse. Survival is expected to approach 100%

Secondary outcome measures
Quality of life, side effects (acute and late)

Overall study start date
13/06/1996

Completion date
13/06/2000

Eligibility

Key inclusion criteria
1. Histologically confirmed seminomatous germ cell tumour of the testis which is classified either as classical or anaplastic (NB patients with combined teratoma/seminoma and spermatocytic seminoma are excluded)
2. Stage 1 disease:
2.1. No evidence of metastatic disease on clinical examination
2.2. Normal chest X-ray
2.3. Normal chest, abdominal and pelvic CT scan
2.4. Normal serum tumour markers (AFP, HCG). Raised HCG pre-orchidectomy does not render a patient ineligible, but a raised AFP does
3. Patients with primary tumour pathologically staged pT1/ pT2/ pT3 are eligible except those with involvement of the cut end of the spermatic cord
4. Patients with previous inguino-pelvic or scrotal surgery have to be treated with dog leg field if randomised to radiotherapy
5. The interval between orchidectomy and randomisation should not exceed 8 weeks
6. No co-existant or previously treated malignant disease, except treated non-melanotic skin cancer
7. No medical condition or other factor preventing adherence to the study schedule and follow-up
8. Consent to be randomised into the proposed study
9. Glomerular filtration rate >40 ml/min

Participant type(s)
Patient

Age group
Not Specified

Sex
Male

Target number of participants
1447

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
13/06/1996

Date of final enrolment
13/06/2000

Locations

Countries of recruitment
Australia

Austria

Belgium

Bosnia and Herzegovina

Denmark

England

France

Israel

Italy

Netherlands

New Zealand

Norway

Poland

Russian Federation

United Kingdom

Study participating centre

Medical Oncology Department
London
United Kingdom
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2005		Yes	No
Results article	results	10/03/2011		Yes	No