

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
Registration date 06/04/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/07/2014	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00003014

Protocol serial number

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 [$7 \times (\text{GFR} + 25)$]
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Time to relapse. Survival is expected to approach 100%

Key secondary outcome(s)

Quality of life, side effects (acute and late)

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-existent 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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

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

United Kingdom

England

Australia

Austria

Belgium

Bosnia and Herzegovina

Denmark

France

Israel

Italy

Netherlands

New Zealand

Norway

Poland

Russian Federation

Study participating centre

Medical Oncology Department

London

United Kingdom

EC1A 7BE

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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