MRC Study of carcinoma in situ of the contralateral testis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/02/2001		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/02/2001	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
18/08/2009	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Pat Cook

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TE11

Study information

Scientific Title

Study objectives

To ascertain the prevalence of CIS of testis in this group of 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

Health condition(s) or problem(s) studied

Cancer

Interventions

All subjects biopsied. Positive biopsy: optional randomisation between radiotherapy or surveillance. Negative biospy: surveillance.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Determine prevalence of CIS and the development of invasive tumour.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1989

Completion date

31/12/1995

Eligibility

Key inclusion criteria

- 1. Germ cell tumour of testis or history of one having been excised in the previous five years
- 2. History of maldescent
- 3. Volume of 12 ml or less in remaining testis

Participant type(s)

Patient

Age group

Not Specified

Sex

Male

Target number of participants

208

Key exclusion criteria

Previous chemotherapy

Date of first enrolment

01/01/1989

Date of final enrolment

31/12/1995

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London United Kingdom NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/1998		Yes	No