ISRCTN78108737 https://doi.org/10.1186/ISRCTN78108737

A phase II trial of docetaxel, cisplatin and 5-fluorouracil (5-FU) chemotherapy in locally advanced and metastatic carcinoma of the penis

Submission date
30/01/2008

Registration date
30/04/2008

Last Edited
26/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/trial-chemotherapy-cancer-penis-penile-tpf

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ICR-CTSU/2008/10016

Study information

Scientific Title
A phase II trial of docetaxel, cisplatin and 5-fluorouracil (5-FU) chemotherapy in locally advanced and metastatic carcinoma of the penis

Acronym
Penile TPF

Study objectives
The goal is to determine, in inoperable cancer of the penis, the feasibility and efficacy of giving chemotherapy consisting of two drugs that are known to be active (cisplatin and 5-fluorouracil [5-FU]) with a newer drug, docetaxel. This combination (TPF) has been proven to be highly active in some similar cancers. This is a limited phase II trial to gain insight into the potential activity of this regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomised controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

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
Penis cancer

Interventions
All participants will receive the same regimen. The regimen consists of docetaxel 75 mg/m2 day 1 + cisplatin 60 mg/m2 day 1 + 5FU 750 mg/m2 days 1-5 with a cycle of 21 days, three cycles to be given in total prior to formal re-staging.

Intervention Type

Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Cisplatin, 5-Fluorouracil, docetaxel

Primary outcome measure
Overall response rate (complete remission rate + partial remission rate). This will be objectively assessed by magnetic resonance imaging (MRI) or computed tomography (CT) scan after completion of the proposed 3 cycles of TPF chemotherapy or at the time of discontinuation of chemotherapy. Scans will be reviewed centrally to confirm outcome.

Secondary outcome measures
1. Proportion of patients with inoperable locoregional disease rendered operable by TPF chemotherapy. Timepoints of measurement not yet defined as of 30 January 2008
2. Progression-free survival. Timepoints of measurement not yet defined as of 30 January 2008.
3. Overall survival. Duration of follow-up not yet defined as of 30 January 2008.
4. Acute toxicity (as determined by Common Toxicity Criteria [CTC]) after each cycle and at 3 months
5. Late toxicity (CTC). Timepoints of measurement not yet defined as of 30 January 2008.

Overall study start date
01/06/2008

Completion date
01/06/2010

Eligibility

Key inclusion criteria
Patients with cancer of the penis fit to receive chemotherapy as palliative or definitive treatment or as treatment on relapse will be eligible. It is expected that the decision to include some groups of patients (e.g., Stage T3, N1 patients) will depend on local policy - discussion within the multidisciplinary Team (MDT) of all eligible patients will be encouraged.

Inclusion criteria:
1. Male, >18 years
2. Histologically-proven squamous cell carcinoma of the penis
3. Eligible disease stage:
3.1. M1
3.2. M0, Tx, N3 (i.e. involvement of deep inguinal or pelvic lymph nodes)
3.3. M0, Tx, N2 (i.e. involvement of multiple or bilateral superficial lymph nodes) and deemed inoperable by MDT
3.4. M0, T3 N1 (tumour invades urethra or prostate and single inguinal lymph node involved)
3.5. M0, T4 (tumour invades other adjacent structures) (any N)
4. Glomerular filtration rate (GFR) greater or equal to 60 ml/min
5. Written, informed consent

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
26

Key exclusion criteria
1. Pure verrucous carcinoma of the penis
2. Squamous carcinoma of the urethra
3. T1 N1 M0 disease
4. T2 N1 M0 disease
5. T3 N1 M0 where the MDT feels that neoadjuvant chemotherapy is not advisable
6. Unfit for this regimen (as assessed by the MDT)
7. Previous chemotherapy
8. Previous radiotherapy (subsequent radiotherapy for loco-regional consolidation is permitted)
9. Contraindication to chemotherapy

Date of first enrolment
01/06/2008

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Haematology & Oncology Centre
Avon
United Kingdom
BS2 8ED

Sponsor information

Organisation
Sponsor not yet defined (UK)

Sponsor details
-
-
United Kingdom
-

Sponsor type
Not defined

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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
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?
Plain English results				No	Yes
Results article	results	12/11/2013		Yes	No