

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

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<b>Registration date</b> 30/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/trial-chemotherapy-cancer-penis-penile-tpf>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Penis cancer

**Interventions**

All participants will receive the same regimen. The regimen consists of docetaxel 75 mg/m<sup>2</sup> day 1 + cisplatin 60 mg/m<sup>2</sup> day 1 + 5FU 750 mg/m<sup>2</sup> 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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Male

**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**

United Kingdom

England

**Study participating centre**

Bristol Haematology & Oncology Centre

Avon

United Kingdom

BS2 8ED

## Sponsor information

**Organisation**

Sponsor not yet defined (UK)

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK

## Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	12/11/2013		Yes	No
<a href="#">Plain English results</a>				No	Yes