ISRCTN61126465 https://doi.org/10.1186/ISRCTN61126465

Randomised trial of Selective bladder Preservation Against Radical Excision (cystectomy) in muscle invasive T2/T3 transitional cell carcinoma of the bladder: a feasibility study

Submission date 17/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/09/2006	**Overall study status** Completed	
Last Edited 03/01/2019	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-surgery-with-treatment-that-may-help-people-to-keep-their-bladder-after-invasive-bladder-cancer

Study website
https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/clinical-trials/spare

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00867347

Secondary identifying numbers
ICR-CTSU/2006/10002

Study information

Scientific Title
Randomised trial of Selective bladder Preservation Against Radical Excision (cystectomy) in muscle invasive T2/T3 transitional cell carcinoma of the bladder: a feasibility study

Acronym
SPARE

Study objectives
Feasibility study: To determine the feasibility and patient acceptability of a multi-centre phase III randomised trial of radical cystectomy versus Selective Bladder Preservation (SBP) and to determine compliance rates with assigned treatment.

Main Trial: To determine if bladder preservation is equivalent to radical cystectomy in responders to neo-adjuvant chemotherapy in terms of overall survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval as of 18/08/2006.

Study design
Randomised multicentre phase III non-inferiority study with an initial feasibility stage

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
Muscle Invasive Bladder Cancer

Interventions
Radical radiotherapy or radical cystectomy

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Feasibility Study:
1. Number of patients randomised over two years
2. Proportion of patients undergoing bladder preservation in SBP arm
3. Proportion of patients undergoing cystectomy in surgery arm

Main Trial:
1. Overall survival

Secondary outcome measures
1. Compliance with randomised treatment
2. Rate of salvage cystectomy after bladder preservation
3. Toxicity
4. Quality of life
5. Loco-regional progression free, metastasis free
6. Overall survival

Overall study start date
01/01/2006

Completion date
12/02/2010

Eligibility

Key inclusion criteria
1. Histologically confirmed Transitional Cell Carcinoma (TCC) of the bladder
2. Aged over 18 years
3. Clinical stage T2 or T3 N0 M0 (as classified by the TNM (Tumour, Nodes, Metastasis) Classification of the American Joint Committee on Cancer [AJCC])
4. World Health Organisation (WHO) performance status zero to one
5. Fit for radical cystectomy
6. Fit for radical radiotherapy
7. Receiving/received three cycles of gemcitabine-cisplatin or other protocol approved neo-adjuvant chemotherapy regimen and willing and fit to receive a fourth cycle according to study protocol

8. Satisfactory haematological profile (at time of chemotherapy administration):
a. Haemoglobin [Hb] more than 10 gms/dl
b. White Blood Cells (WBC) more than 3.0 x 10^9/L
c. Platelet count more than 150 x 10^9/L
9. Liver function tests (Bilirubin, Aspartate Aminotransferase [AST], Alkaline phosphatase less than 1.5 x Upper Limit of Normal [ULN])
10. Written informed consent and available for long-term follow-up
11. Patients receiving chemotherapy are expected to have a glomerular filtration rate more than 50 ml/min though this is not part of formal inclusion criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110 patients in the feasibility study

Key exclusion criteria
1. Adenocarcinoma, Squamous Cell Carcinoma (SCC), small cell carcinoma or other variant histology (N.B. squamoid differentiation or mixed TCC/SCC is permitted)
2. Widespread Carcinoma In Situ (CIS) or CIS remote from muscle invasive tumour
3. Previous malignancy in the last five years except for adequately controlled non melanotic skin tumours, CIS of cervix or Lobular Carcinoma In Situ (LCIS) of breast
4. Pre-exisiting hydronephrosis
5. Previous pelvic radiotherapy
6. Any contra-indication to radical radiotherapy e.g. inflammatory bowel disease, radiosensitivity syndrome, severe diverticular disease
7. Bilateral total hip replacements
8. Pregnancy
9. Significant co-morbid medical conditions which would interfere with administration of any protocol treatment

Date of first enrolment
01/01/2006

Date of final enrolment
12/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
ICR-CTSU
Sutton
United Kingdom
SM2 5NG

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

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

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (ref: C1198)

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

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.
Contact details are the same as in the contact information section. Clinical data are available for sharing subject to completion of a data sharing application form, approval by the trial oversight committees and completion of a data sharing agreement. As part of the review the trialists would consider whether the existing trial consent covers the application, what anonymisation will be required and whether separate ethics approval would be required.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	15/03/2011		Yes	No
Results article	results	01/11/2017		Yes	No