ISRCTN84013636 https://doi.org/10.1186/ISRCTN84013636

Photodynamic versus white light-guided treatment of non-muscle invasive bladder cancer

Submission date 25/07/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/07/2014	**Overall study status** Completed	
Last Edited 26/04/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-white-light-blue-light-surgery-people-bladder-cancer-photo

Contact information

Type(s)
Scientific

Contact name
Mr Steven Penegar

Contact details
Clinical Trials & Statistics Unit at the Institute of Cancer Research (ICR-CTSU)
The Institute of Cancer Research
London
United Kingdom
SM2 5NG
-
PHOTO-icrctsu@icr.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17055

Study information

Scientific Title
PHOTOdynamic versus white light-guided treatment of non-muscle invasive bladder cancer: randomised trial of clinical and cost-effectiveness

Acronym
PHOTO

Study objectives
Bladder cancer is a high priority area for research into clinical and cost-effective management and the findings from the PHOTO trial are likely to remain highly relevant and important to the needs of the NHS over the next 20 years, the expected life span of the equipment for the PDD technology. A further compelling reason for the study is the current piecemeal adoption of PDD within the NHS, resulting in variation in provision of PDD service. This gives further urgent need for better quality evidence to guide providers of bladder cancer services and the relevant practice guidance authorities to make early decisions around wholesale adoption or disinvestment in PDD technology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 2, 16/07/2014, ref: 14/NE/1062

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Topic: Cancer; Subtopic: Bladder Cancer; Disease: Bladder (superficial)

Interventions

Randomisation will be undertaken centrally using either the secure web-based or the 24-hour Interactive Voice Response randomisation system at the Centre for Healthcare Randomised Trials (CHaRT) in Aberdeen, using minimisation by centre and gender, to allocate participants 1:1 to the control and experimental groups. The minimisation algorithm will incorporate a random element in order to prevent deterministic treatment allocation.

Guidance on treatment and follow up of NMIBC, developed by the European Association of Urology (EAU), recommend that patients who have high risk disease, or where there are indications that the TURT may not have been complete, should have a further resection of the original disease site 26 weeks after initial treatment. This reresection is intended to ensure that the initial resection was as complete as possible and to check that muscle invasive disease, which would require further radical treatment, has not been missed. Following initial or reresection, patients in both intermediate and high risk groups are recommended to receive further (adjuvant) intravesical treatment with the aim of reducing the risk of future recurrence and progression. Patients in the intermediate risk group are usually given further treatment with chemotherapy once a week for 6 weeks. Patients in the high risk group are treated with intravesical immunotherapy weekly for 6 weeks and may have further treatments every few months for up to 3 years. Patients will have 3 monthly cystoscopies to check for any sign of recurrence for 2 years, then 6 monthly to five years, after which they will continue to be followed up annually.

PHOTO follow-up schedule
All participants will be followed up according to EAU guidelines, with regular cystoscopies initially 3 monthly following surgery (either initial TURT or second TURT for those who have one). The PHOTO trial will collect the following information at the 3,6,9,12,18,24 and 36 month routine visits:
1. Outcome of cystoscopy
2. Adverse event information
Participants will be asked to complete quality of life and health service utilisation questionnaires 3, 6, 12, 18, 24 and 36 months post randomisation. Participants will also be asked to complete a patient costs questionnaire 30 months after randomisation. Questionnaires will be posted to patients homes by CHaRT.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
1. To compare time to recurrence, for each of the two treatment strategies, with a principal point of interest at 3 years.
2. To evaluate cost effectiveness by the incremental cost for recurrence avoided and cost utility as the incremental cost per quality adjusted life year (QALY) gained at three years.

Secondary outcome measures
Secondary objectives will further explore clinical and cost effectiveness of photo dynamic surgery:
Clinical effectiveness:

1. Measure relative rate of disease progression at 3 years
2. Measure relative harms and safety
3. Measure health-related quality of life (HRQoL) and cancer specific survival

Overall study start date
01/09/2014

Completion date
23/06/2021

Eligibility

Key inclusion criteria
1. Adult men and women aged ≥ 16 years
2. First suspected diagnosis of bladder cancer
3. Visual/ultrasound/CT diagnosis of intermediate/high risk NMIBC
3.1. White light visual appearances of intermediate or high risk disease (=> 3cm, two or more tumours, or flat velvety erythematous changes alerting a clinical suspicion of CIS).
3.2. Suspicion of papillary bladder tumour > 3cm based on ultrasound or computerized tomography (CT) scanning (without hydronephrosis)
4. Written informed consent for participation prior to any study specific procedures
5. Willing to comply with lifestyle guidelines

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 533; UK Sample Size: 533

Total final enrolment
538

Key exclusion criteria
1. Visual evidence of low risk NMIBC (solitary tumour < 3cm)
2. Visual evidence of MIBC on preliminary cystoscopy, i.e. nonpapillary or sessile mass (attached directly by its base without a stalk)
3. Imaging evidence of MIBC CT/USS (this includes the presence of hydronephrosis, which may be present despite clear imaging of MIBC in the bladder)
4. Upper tract (kidney or ureteric) tumours on imaging
5. Any other malignancy in the past 2 years (except: nonmelanomatous skin cancer cured by excision, adequately treated carcinoma in situ of the cervix, DCIS/LCIS of the breast or prostate cancer in patients who have a life expectancy of >5 years upon trial entry)
6. Evidence of metastases
7. Porphyria or known hypersensitivity to porphyrins

8. Known pregnancy (based on history and without formal testing, in keeping with day-to-day NHS practice of PDD use)
9. Any other conditions that in the Principal Investigators opinion would contraindicate protocol treatment
10. Unable to provide informed consent
11. Unable or unwilling to complete follow up schedule (including questionnaires)

Date of first enrolment
23/10/2014

Date of final enrolment
14/02/2018

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Churchill Hospital
Old Road
Oxford
United Kingdom
OX3 7LE

Study participating centre
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD2 1UB

Study participating centre
University College Hospital London
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Princess Of Wales Hospital
Coity Road
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
St Peter's Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Castle Hill Hospital
Castle Road

Cottingham
United Kingdom
HU16 5JQ

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
James Cook University Hospital
Marton Road
Middlesborough
United Kingdom
TS4 3BW

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Swansea
United Kingdom
SA6 6NL

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Barnet General Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Northern Centre for Cancer Care
Freeman Road
High Heaton
Newcastle upon Tyne
England
United Kingdom
NE7 7DN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The main trial results will be published in a peer-reviewed journal.

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/09/2019	05/10/2020	Yes	No
Results article		02/09/2022	27/09/2022	Yes	No
Results article		01/10/2022	28/10/2022	Yes	No
HRA research summary			28/06/2023	No	No