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A randomised study of 'bluelight' hexyl aminolevulinic acid (HAL) photodynamic assisted resection of bladder tumours versus conventional 'whitelight' transurethral resection of newly diagnosed bladder tumours comparing rates of tumour recurrence over one year - a Phase IV trial

Submission date 25/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/09/2005	**Overall study status** Completed	
Last Edited 19/11/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04/QO603/42

Study information

Scientific Title
A randomised study of 'bluelight' hexyl aminolevulinic acid (HAL) photodynamic assisted resection of bladder tumours versus conventional 'whitelight' transurethral resection of newly diagnosed bladder tumours comparing rates of tumour recurrence over one year - a Phase IV trial

Study objectives
The aim is to determine if photodynamic assisted resection can reduce the recurrence rate of tumour at one year when compared with the control group. The primary endpoint is the diagnosis of recurrent tumour at 3 months or 12 months on check cystoscopy.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bladder cancer

Interventions
Intervention: Pre-operative intravesical instillation of solution of hexylaminolevulinic acid (HAL) - photodynamic 'bluelight' assisted resection of bladder tumours
Control: Conventional 'whitelight' transurethral resection

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Hexyl aminolevulinic acid (HAL)

Primary outcome measure
Recurrence rates of bladder tumour at 3 months and 12 months post surgery

Secondary outcome measures
Analysis of histology

Overall study start date
01/02/2005

Completion date
01/02/2007

Eligibility

Key inclusion criteria
1. New diagnosis of bladder tumour - the study is designed to reduce recurrence rates in newly diagnosed cases of bladder tumours
2. Superficial disease - the study will address the recurrence rates in superficial bladder cancer
3. No history of previous bladder surgery - previous surgical procedures to the bladder may cause artifactual changes when using 'blue light' cystoscopy
4. Life expectancy of at least 1-year - study duration will be for 1-year

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200 (100 in each group)

Key exclusion criteria

1. Previous bladder tumour or coexisting/previous upper tract disease - the study is designed to reduce recurrence rates in newly diagnosed cases of bladder tumours
2. Muscle invasive disease - the study will address the recurrence rates in superficial bladder cancer
3. Previous bladder surgery -previous surgical procedures to the bladder may cause artifactual changes when using 'blue light' cystoscopy

Date of first enrolment
01/02/2005

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's Hospital - Research and Development Department (UK)

Sponsor details
Ground Floor
West Wing Counting House
Guy's Hospital
St Thomas' Street
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/04r33pf22

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity (UK)

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?
Results article	results	01/12/2013		Yes	No