

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/11/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

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