

An investigation of proteins found in urine and blood to identify a combination of proteins which will detect bladder cancer

Submission date 30/12/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
ORECNI 80/04

Study information

Scientific Title

Evaluation and comparison of urine markers to investigate the development of a diagnostic index for bladder cancer

Study objectives

A combination of proteins secreted into urine and/or blood will be able to identify patients with bladder cancer

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office for Research Ethics Committees Northern Ireland (80/04)

Study design

Observational case control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Haematuria in bladder cancer

Interventions

This study recruited 200 patients who had reported blood in their urine to their doctor. Half of these patients had a final diagnosis of bladder cancer and the other half had other diagnoses. Blood and urine was taken from each patient. The levels of different proteins in the urine and blood were measured on anonymised blood and urine samples by a company called Randox Laboratories Ltd.

Intervention Type

Other

Primary outcome measure

1. To compare specificities and sensitivities of the TCCB markers and generic cancer markers in predicting TCCB
3. To retain a bank of urine and blood samples if the need arise to assay further markers
4. To determine the best combination of factors for a prognostic index for TCCB

Secondary outcome measures

To compare biomarkers as prognostic indicators for TCCB

Overall study start date

01/09/2004

Completion date

31/10/2009

Eligibility

Key inclusion criteria

1. Patients with haematuria who have undergone cystoscopy
2. Patients must be able to understand the study procedures and willing to give informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Patients who have not had a flexible cystoscopy
2. Patients who did not present with haematuria
3. Patients with UTI destined to undergo TURB
4. Patients currently suffering from clinically evident alcoholism and or drug dependency

Date of first enrolment

13/11/2006

Date of final enrolment

22/04/2008

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre

Belfast City Hospital

51 Lisburn Road

Belfast

United Kingdom

BT9 7AB

Study participating centre

Carigavon Area Hospital

68 Lurgan Road

Portadown

United Kingdom

BT63 5QQ

Sponsor information

Organisation

Belfast City Hospital Trust

Sponsor details

Lisburn Road

Belfast

Northern Ireland

United Kingdom

BT9 7AD

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02405mj67>

Funder(s)

Funder type

Industry

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration.

Intention to publish date

01/01/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration