

INSTITUTIONAL REVIEW BOARD STATEMENT

Name of Journal: *World Journal of gastrointestinal Endoscopy*

Manuscript NO: 35509

Manuscript type: Observational Study

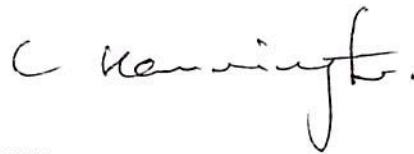
Mediastinal node staging by CT-PET and selective EUS-FNA for patients with upper gastrointestinal cancer: results from a regional centre

Chris Harrington, Lyn Smith, Jennifer Bisland, Elisabet López González, Neil Jamieson, Stuart Paterson, Adrian John Stanley

Institutional Review Board Statement: This study was discussed with Dr Judith Godden at the West of Scotland Research Ethics Service. She has advised that no ethical approval is required as this retrospective project is an audit rather than a research project.

Name: Dr Chris Harrington

Signature:

A handwritten signature in black ink, appearing to read 'C Harrington', written over a horizontal line.

Date: 20/10/2017

From: "HARRINGTON, Chris (NHS GREATER GLASGOW & CLYDE)" <chrisharrington@nhs.net>
Date: 02 November 2017 18:28
To: <chris973@doctors.org.uk>
Subject: Fw: Ethics approval for endoscopy audit at GRI

From: HARRINGTON, Chris (NHS LANARKSHIRE)
Sent: 01 December 2016 08:52
To: Brown, Isobel
Subject: Re: Ethics approval for endoscopy audit at GRI

Thanks

Chris

From: Brown, Isobel <Isobel.Brown@ggc.scot.nhs.uk>
Sent: 29 November 2016 14:35
To: HARRINGTON, Chris (NHS LANARKSHIRE)
Subject: RE: Ethics approval for endoscopy audit at GRI

Hi Chris

I note Judith's comments and can confirm that I don't require you to seek Caldicott approval for the audit as it has already been carried out.

You would not require IG permission to publish findings.

Regards

Isobel

From: Godden, Judith
Sent: 29 November 2016 11:47
To: 'HARRINGTON, Chris (NHS LANARKSHIRE)'
Cc: Brown, Isobel
Subject: RE: Ethics approval for endoscopy audit at GRI

Dear Chris

Thank you for following up with further information. I think we can define this project as audit and therefore no NHS ethical review is required. I have copied in our Information Governance Manager.

Kind regards

Judith

From: HARRINGTON, Chris (NHS LANARKSHIRE) [<mailto:chrisharrington@nhs.net>]
Sent: 27 November 2016 16:29
To: Godden, Judith
Subject: Re: Ethics approval for endoscopy audit at GRI

Hi Judith

Thanks for getting back to me.

We think of our study as a retrospective audit of clinical outcomes.

The audit looked retrospectively at the results of PET-CT and endoscopic ultrasound (EUS) for patients diagnosed with upper GI cancer. It is guideline based standard of care for all patients with this diagnosis whom are potentially for curative treatment to have both these investigations. All of our cases had both of them.

The purpose of the audit was to compare the sensitivity, specificity, positive predictive value and negative predictive value of PET-CT in the detection of malignant lymph nodes local to the primary tumour in the mediastinum with values reported in previous studies. The gold standard for malignant lymph nodes was the pathology specimen obtained by the EUS.

We found that PET-CT has very high levels of sensitivity and negative predictive value in this setting but much poorer specificity and positive predictive value. We concluded that if PET-CT was used alone in these patients, many patients would have inaccurate tumour staging (overstaging) and would be denied potentially curative treatment. Our findings therefore support the advice given in the clinical guidelines.

Thanks again

Chris

From: Godden, Judith <Judith.Godden@ggc.scot.nhs.uk>
Sent: 25 November 2016 15:30

To: HARRINGTON, Chris (NHS LANARKSHIRE)
Subject: RE: Ethics approval for endoscopy audit at GRI

Dear Chris

Can you tell me the purpose of the audit? Only research requires ethical approval but we have a very specific definition of audit (usually comparing against a standard) therefore it is worth checking the aims of the audit.

This involves patient data therefore you should run this past the Caldicott Guardian (Isobel Brown from Information Governance will be able to help you with this)

Kind regards

Judith

Dr Judith Godden
Manager/Scientific Officer
West of Scotland Research Ethics Service
Clinical Research & Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow G3 8SW

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 e-mail: judith.godden@ggc.scot.nhs.uk

From: HARRINGTON, Chris (NHS LANARKSHIRE) [<mailto:chrisharrington@nhs.net>]
Sent: 23 November 2016 08:49
To: Godden, Judith
Subject: Ethics approval for endoscopy audit at GRI

Dear Dr Godden

My name is Chris Harrington, I am a gastroenterology registrar doc in the west of Scotland deanery, currently at Forth Valley hospital. I am writing to ask you if I need specific ethics approval to submit for publication a retrospective audit I performed when I was working at GRI earlier this year.

The audit involved collecting data retrospectively for patients over the last 6 years who had investigations (PET-CT and endoscopic ultrasound) for the staging of their diagnosis of oesophageal cancer. We recorded no patient specific data. We also collected data on survival outcomes.

I could send you a copy of my manuscript if this helps?

Kind regards

Chris Harrington

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