# 5-ALA in bowel cancer surgery

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
04/04/2013		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/04/2013	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
25/04/2019	Cancer			

## Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-5ala-in-bowel-cancer-surgery-glisten

## Contact information

## Type(s)

Scientific

#### Contact name

Prof David Jayne

#### Contact details

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## Additional identifiers

## EudraCT/CTIS number

2012-002623-15

**IRAS** number

ClinicalTrials.gov number

## Secondary identifying numbers

14209; EME 11/100/24

# Study information

#### Scientific Title

GLiSten: Next generation intraoperative lymph node staging for stratified colon cancer surgery - development phase

#### Acronym

GLiSten

## **Study objectives**

The study is looking at the use of 5-aminolevulinic acid (5-ALA) in bowel cancer. 5-ALA will not be used to treat the cancer but used during the operation to detect the cancer along with any spread to lymph nodes that surround the bowel as it is preferentially taken up into cancer cells.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/eme/1110024 /#/

Protocol can be found at: https://njl-admin.nihr.ac.uk/document/download/2005810

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NRES Committee London - South East, 20/03/2013, ref: 13/LO/0214

## Study design

Non-randomised; Interventional; Design type: Treatment

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Colon

#### **Interventions**

5-ALA will be given as a drink approximately 4 hours before surgery and it is thought that any cancer cells in the bowel and in the lymph nodes will glow red under a blue light.

The surgical specimen will be pathologically reviewed and the areas with confirmed cancer cells will be compared to areas that glowed red to see how accurately the substance (5-ALA) detects bowel cancer.

5-ALA has been used extensively before in other cancers, such as bladder cancer, brain tumours, and ovarian cancer. It has only been used before on a very small scale in colorectal cancer.

The study will first run as a Development phase to standardize the techniques, in two centres (Leeds and Dublin), recruiting at least 30 patients with positive lymph nodes. The trial will then expand to an Evaluation phase at approximately 8 centres recruiting 300 patients.

Follow Up Length: 1 month(s)

#### Intervention Type

Drug

#### Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

5-aminolevulinic acid

#### Primary outcome measure

Identification of the optimal dose for oral administration of 5-ALA for the accurate intraoperative; Timepoint(s): November 2014

## Secondary outcome measures

- 1. Standardisation of preoperative CT reporting, with emphasis on lymph node evaluation
- 2. Standardisation of operative procedure including D3 lymphadenectomy
- 3. Optimisation and standardisation of fluorescence detection system
- 4. Standardisation of pathological lymph node mapping and step sectioning for in depth lymph node evaluation
- 5. Patient factors affecting the accuracy of 5-ALA fluorescence diagnosis
- 6. Safety

## Overall study start date

01/06/2013

## Completion date

30/11/2014

# Eligibility

#### Key inclusion criteria

- 1. Able to give informed consent and willing to follow trial protocol
- 2. Aged over 18
- 3. Patients with cancers of the right and sigmoid colon amenable to laparoscopic resection incorporating D3 lymphadenectomy, as agreed by MDT discussion following histopathological diagnosis and radiological staging. Where possible, the study population will be enriched with locally advanced colon cancers to obtain as much information as possible on 5-ALA Fluorescence diagnosi (FD) for lymph node metastases

- 4. Patients with distant metastatic disease will be eligible, provided laparoscopic resection of the cancer is part of routine clinical care
- 5. Fit for standard laparoscopic resection
- 6. American Society of Anesthesiologists (ASA) classification <= 3
- 7. Normal hepatic and renal function
- 7.1. Total bilirubin within normal institutional limits, AST/ALT < 2.5 X institutional upper limit of normal
- 7.2. Creatinine within normal institutional limits

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

## Target number of participants

Planned Sample Size: 52; UK Sample Size: 26

#### Key exclusion criteria

- 1. Patients with cancers of the transverse and left colon (due to difficulty in defining D3 lymphadenectomy in these anatomical locations)
- 2. Past history of hypersensitivity reactions to 5-ALA or colorimetric dye
- 3. Acute or chronic porphyria or a family history
- 4. Patients with synchronous colonic or rectal cancer (but not benign polyps)
- 5. Patients with coexistent inflammatory bowel disease, such as Crohns disease, ulcerative colitis or active diverticulitis, which may influence the lymphatic uptake of 5-ALA
- 6. Pregnant (positive pregnancy test) or breast feeding. 5-ALA has unknown teratogenic and abortifacient effects.
- 7. Received an investigational medicinal product at any dose within 28 days before registration
- 8. Poorly controlled or serious medical or psychiatric illness that, in the Investigators opinion, is likely to interfere with participation and/or compliance in this clinical trial

#### Date of first enrolment

01/06/2013

#### Date of final enrolment

30/11/2014

## Locations

## Countries of recruitment

England

Ireland

## **United Kingdom**

Study participating centre
University of Leeds & Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS9 7TF

# Sponsor information

## Organisation

University of Leeds (UK)

#### Sponsor details

c/o Neville Young, 34 Hyde Terrace Leeds England United Kingdom LS2 9LN

#### Sponsor type

University/education

## Website

http://www.leeds.ac.uk

#### **ROR**

https://ror.org/024mrxd33

# Funder(s)

## Funder type

Government

#### **Funder Name**

Efficacy and Mechanism Evaluation Programme

#### Alternative Name(s)

NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

## **Funding Body Type**

## Government organisation

## **Funding Body Subtype**

National government

#### 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

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	01/08/2016		Yes	No
HRA research summary			28/06/2023	No	No