ISRCTN79949827 https://doi.org/10.1186/ISRCTN79949827

5-ALA in bowel cancer surgery

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

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
University of Leeds & Leeds Teaching Hospitals NHS Trust
Section of Translational Anaesthesia & Surgery
Beckett Street
Leeds
United Kingdom
LS9 7TF
-
d.g.jayne@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2012-002623-15

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Ireland

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

Sponsor information

Organisation

University of Leeds (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes