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The STAT-ROC feasibility study

Submission date 08/01/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/01/2015	**Overall study status** Completed	
Last Edited 06/02/2020	**Condition category** Cancer	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2014-001318-24

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17147

Study information

Scientific Title

A feasibility study of adjuvant STATin therapy in the prevention of postoperative Recurrence of Oesophageal adenoCarcinoma (The STATROC feasibility study)

Acronym
STATROC

Study hypothesis
This study is a single-centre, blinded, parallel group, randomised controlled trial to determine the feasibility of investigating adjuvant statin therapy in the prevention of post-operative recurrence of oesophageal and gastro-oesophageal adenocarcinoma in a future phase III RCT. Patients who have undergone potentially curative surgery will be randomised to receive either simvastatin 40mg nocte or placebo on discharge from hospital for one year. Participants will be assessed at screening, baseline and at months 3, 6, 9 and 12. Assessments will include measurements of recruitment and retention, absorption, adherence, safety, quality of life, disease-free and overall survival and generalisability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SC/0247; First MREC approval date 01/07/2014

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Condition
Topic: Cancer; Subtopic: Upper Gastro-Intestinal Cancer; Disease: Oesophagus

Interventions
Placebo, Microencapsulated lactose tablets, oral administration nocte; Simvastatin 40mg, Microencapsulated generic simvastatin film coated tablets, 40mg, oral administration nocte; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Absorption; Timepoint(s): LDL cholesterol at 3, 6, 9 and 12 months from discharge from hospital following surgery

Secondary outcome measures
1. Adherence; Timepoint(s): Pill counts at 3, 6, 9 and 12 months from discharge from hospital following surgery
2. Generalisability; Timepoint(s): Screening and Baseline visits;
3. Overall and disease-free survival; Timepoint(s): Up to one year post-discharge following surgery
4. Quality of life; Timepoint(s): Baseline, 3, 6, 9 and 12 months post-discharge following surgery.
5. Recruitment; Timepoint(s): Measured between 21/10/14 and 31/10/15
6. Retention; Timepoint(s): Measured between randomisation of first participant and date of end of follow-up (latest 31/10/16)
7. Safety; Timepoint(s): Adverse events will be continuously recorded from the date of first trial medication administration

Overall study start date
21/10/2014

Overall study end date
31/10/2015

Eligibility

Participant inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, aged 18 years or above
3. Diagnosed with oesophageal adenocarcinoma (including adenocarcinoma of the gastrooesophageal junction [Siewert 1 or 2 lesions]) confirmed with both endoscopy and histology
4. Due to undergo potentially curative surgery with either an oesophagectomy, oesophagogastrectomy or extended total gastrectomy and survive to discharge from hospital following their operation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 36; UK Sample Size: 36; Description: As this is a feasibility study a formal sample size calculation is not required.

Total final enrolment
32

Participant exclusion criteria
1. Currently prescribed a statin as part of their routine clinical care
2. Due to be prescribed a statin as part of their routine clinical care. Applicable to a participant who has agreed to statin therapy as recommended by their general practitioner (GP) for the primary or secondary prevention of cardiovascular disease. NB: patients who qualify for a statin but who choose not to be prescribed one for primary or secondary prevention of cardiovascular disease are still potentially eligible for this study
3. Hypersensitivity to simvastatin
4. Active liver disease or unexplained persistent elevations of serum transaminases (> 3x uppler limit of normal [ULN])
5. Severe renal insufficiency (estimated glomerular filtration rate [eGFR] less than 30 mL/minute /1.73 m2).
6. Creatine kinase (CK) > 5x ULN
7. Female participant who is pregnant, lactating or planning pregnancy during the course of the trial
8. Concomitant drug prescription of potent CYP3A4 inhibitors planned for greater than 1 month during the study period (e.g. itraconazole, ketoconazole, fluconazole, posaconazole, HIV protease inhibitors [e.g. nelfinavir], erythromycin, clarithromycin, telithromycin and nefazodone)
9. Concomitant drug prescription planned for greater than 1 month during the study period of amiodarone, verapamil, diltiazem, amlodipine, ciclosporin, danazol or gemfibrozil
10. Acute porphyria

Recruitment start date
21/10/2014

Recruitment end date
31/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Earlham Road
Norwich

United Kingdom
NR4 7TJ

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust

Sponsor details
Colney Lane
Colney
Norwich
England
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NR4 7UY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017		Yes	No
Results article	results	01/02/2020	06/02/2020	Yes	No
HRA research summary			28/06/2023	No	No