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Liver resection surgery versus thermal ablation for colorectal liver metastases

Submission date 09/03/2016	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/03/2016	**Overall study status** Stopped	
Last Edited 11/05/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-surgery-ablation-treatment-people-bowel-cancer-spread-liver-lava

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20592

Study information

Scientific Title
LAVA: Liver resection surgery versus thermal Ablation for colorectal liVer metAstases

Acronym
LAVA

Study objectives
The aim of this study is to compare the effectiveness of liver resection surgery and thermal ablation for the treatment of colorectal liver metastases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
16/LO/0058

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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: Surgery; Subtopic: Surgery; Disease: Surgery (All Surgery)

Interventions
Participants are randomly allocated to one of two treatment groups.

Surgical resection: Surgical liver resection will be performed in accordance with each site’s usual practice. Patients may be offered open or laparoscopic liver resection depending on site and stage of disease. Procedures for patients with extensive metastatic disease can include two stage liver resection, venous embolization, or the ALPPS procedure (Associated Liver Partition and Portal vein ligation for Staged hepatectomy).

Thermal ablation: Either radiofrequency ablation (RFA) or microwave ablation (MWA) will be carried out according to the local availability of equipment and expertise. Ablation may be performed at laparoscopic or open surgery if the percutaneous approach is contra-indicated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Disease free survival at 2 years is calculated from participant assessments at 3, 6, 12, 18 and 24 months post-randomisation

Secondary outcome measures
1. Local and distant recurrence of disease at 2 years is calculated from participant assessments at 3, 6, 12, 18 and 24 months post-randomisation
2. Overall survival is determined at 2 and 5 years post-randomisation
3. Post treatment complications are recorded at participant assessments at 3, 6, 12, 18 and 24 months post-randomisation
4. Disease free survival (DFS) (measured from end of intervention) at 2 years post-randomisation
5. Use of subsequent therapies for treatment failure over 2 years post-randomisation
6. Health related quality of life is measured using EQ-5D, EORTC QLQ-C30, EORTC LMC21 at baseline 3 and 6 months post randomisation
7. Length of intensive therapy unit (ITU) and inpatient stay
8. Resource use collected retrospectively at 3, 6, 12, 18, and 24 months post-randomisation

Overall study start date
01/10/2016

Completion date
30/09/2020

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years
2. Able to provide written informed consent
3. MDT diagnosis of colorectal liver metastases considered to be resectable with curative intent
4. Resected colorectal primary or plan for primary resection with curative intent
5. Meets one or more of the following criteria:
5.1. Considered high risk for surgery due to age e.g. Age greater than 75 years of age
5.2. Major co-morbidities as judged by the treating clinician. Examples include history of myocardial infarction, severe chronic airway disease, major cerebrovascular accidents (CVA), pulmonary embolism (PE)
5.3. Liver metastases with poor prognosis and or high risk surgery due to tumour burden, Examples include extensive synchronous disease, need for two stage resection or ALLPS, small anticipated remnant liver volume, resectable or ablatable extra-hepatic disease, downstaged with chemotherapy, poor response after chemotherapy or portal vein embolization but still resectable

6. Suitable candidate for either liver resection surgery or thermal ablation as judged by the MDT
7. Able and willing to comply with the terms of the protocol including QoL questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 330; UK Sample Size: 252

Total final enrolment
9

Key exclusion criteria
1. Incurable extra-hepatic metastases
2. Concurrent malignant disease (except basal cell carcinoma)
3. Patients who have undergone previous surgery or ablation for colorectal liver metastases
4. Planned simultaneous resection for primary and liver metastases disease
5. Pregnancy

Date of first enrolment
01/10/2016

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Clinical Trials Research Unit
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Sponsor information

Organisation
University College London

Sponsor details
R&D (1st Floor, Maple House)
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NW1 2BU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

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
31/08/2019

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?
Protocol article	protocol	13/02/2018		Yes	No
Results article	results	01/04/2020	11/05/2020	Yes	No
HRA research summary			28/06/2023	No	No