

Liver resection surgery versus thermal ablation for colorectal liver metastases

Submission date 09/03/2016	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/03/2016	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/05/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

Ms Julie Croft

Contact details

University of Leeds
Clinical Trials Research Unit
17 Springfield Mount
Leeds
United Kingdom
LS2 9JT

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

30/09/2020

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Aged \geq 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

University of Leeds

Clinical Trials Research Unit

17 Springfield Mount

Leeds

United Kingdom

LS2 9JT

Sponsor information

Organisation

University College London

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

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