ISRCTN52040363 https://doi.org/10.1186/ISRCTN52040363

# Liver resection surgery versus thermal ablation for colorectal liver metastases

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|---|---|---|
| **Submission date**<br>09/03/2016 | **Recruitment status**<br>Stopped | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>09/03/2016 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>11/05/2020 | **Condition category**<br>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)
Rossenheim Building
235 Euston Road
London
England
United Kingdom
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 |