HARMONY

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To demonstrate the feasibility of single session minimally invasive concurrent robotic liver resection and cone beam CT-guided percutaneous ablation of colorectal liver metastases in a hybrid operating room and evaluate its outcomes.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary therapeutic procedures
Study type	Interventional research applied for the first time in human subjects

Summary

ID

NL-OMON57678

Source
Onderzoeksportaal

Brief title
HARMONY

Condition

- Hepatobiliary therapeutic procedures
- Hepatobiliary neoplasms
- Hepatic and hepatobiliary disorders

Synonym
colorectal liver metastasis; liver tumours

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Surigical procedure

Explanation

N.a.

Outcome measures

Primary outcome

The main study endpoint is feasibility of the HARMONY procedure, defined as the technical success of both the robotic surgical resection and C-arm CT-guided ablation within the hybrid operating room. Surgical technical success is defined as treatment according to protocol and full resection of the target lesion confirmed using ICG fluorescence imaging. Ablation technical success is defined as treatment according to protocol and lesion covered completely by the ablation zone, confirmed using ablation confirmation software.

Secondary outcome

Other study parameters include short-term periprocedural outcomes, including morbidity.

Study description

Background summary

Surgical resection and ablation offer patients with colorectal liver metastasis (CRLM) the only chance for cure. In select patients with multiple metastases, combined ablation and resection offers the potential for complete hepatic disease clearance, while avoiding the need for extensive liver resections. The current state-of-the-art in liver surgery for CRLM is robotic liver resection with ICG fluorescence imaging. For ablation of CRLM, the gold standard is CT-guided ablation with hepatic arteriography and ablation margin assessment. When both resection and ablation are necessary in the treatment of CRLM, these procedures are typically performed sequentially, leading to two anaesthesia inductions and separate recovery phases. While performing these procedures concurrently could address these drawbacks, it comes with significant technical and logistical challenges. The integrated environment of a hybrid operating room may facilitate the seamless combination of these two procedures in a single session.

Study objective

To demonstrate the feasibility of single session minimally invasive concurrent robotic liver resection and cone beam CT-guided percutaneous ablation of colorectal liver metastases in a hybrid operating room and evaluate its outcomes.

Study design

This study is a prospective observational cohort study in which a novel treatment strategy (single-session robotic liver resection and cone beam CT-guided percutaneous ablation) will be implemented following the IDEAL framework for surgical innovation.

Intervention

Concurrent robotic resection and cone beam CT-guided percutaneous ablation in a hybrid operating room.

Study burden and risks

No additional risks are associated with participation, as combining the procedures is not expected to introduce new risks beyond the known risks inherent to each procedure individually. Perioperative care will occur according to standard practice and no additional data will be gathered rather than the data already collected in the context of the normal clinical routine. Potential benefits of participation are the advantages associated with concurrent procedures including, single anaesthesia induction, shorter total procedure time, and faster recovery.

Contacts

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Trial sites

Trial sites in the Netherlands

Amsterdam UMC
Target size: 15

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)
Adults (18-64 years)

Inclusion criteria

Adults (≥18 years of age), eligible for local treatment of colorectal liver metastases using a combination of robotic resection and CT-guided ablation

Exclusion criteria

- Any contraindication for robotic liver resection or CT-guided percutaneous ablation of colorectal liver metastases.
- No informed consent.

Study design

Design

Study phase:	N/A
Study type:	Interventional research applied for the first time in human subjects
Intervention model:	Single
Allocation:	N/A: single arm study

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2025
Enrollment:	15
Duration:	18 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	22-05-2025
Application type:	First submission
Review commission:	METC Amsterdam

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Research portal	NL-009169