

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the Outcomes and Complications of Two transection techniques (Crush-Clamp versus Ultrasonic Dissection) for Hepatic resection in Patients with Hepatic Mass

Protocol summary

Study aim

Comparison of the Outcomes and Complications of Two transection techniques (Crush-Clamp versus Ultrasonic Dissection) for Hepatic resection in Patients with Hepatic Mass in Golestan Hospital

Design

This clinical trial has a control group, with parallel groups, double-blind and random. Patient and data analyzer are not aware of the techniques of surgery. In the control group, patients underwent hepatectomy using crush-clamp. The intervention group underwent Ultrasonic dissection.

Settings and conduct

In this double blind study, patient and data analyzer have no information about surgical technique. The study is being conducted at Golestan Hospital in Ahvaz. As the type of tumor and hepatectomy have a effect on the complications and outcome, we try to identify the two groups in terms of tumor type and hepatectomy type. After selecting the procedure, from the start of operation, all variables including operative time, hepatectomy time, bleeding rate, intraoperative and postoperative blood gases changes, intraoperative and postoperative urine output, postoperative liver enzyme profiles, The patient's INR is recorded postoperatively and compared with each other. The amount of daily discharge and color of the patient's drain is also recorded. If the patient dies, the cause is stated. Patients will be ultrasound on day 3 and 30 postoperatively and compared for intra-abdominal abscess. Patients will be followed for 30 days after discharge and the results will be analyzed by SPSS software.

Participants/Inclusion and exclusion criteria

Patients undergoing hepatectomy are included in the study. If the patient is not satisfied, he will not be included in the study.

Intervention groups

In the control group, patients underwent hepatectomy using crush-clamp. The intervention group underwent Ultrasonic dissection.

Main outcome variables

operation time: hepatectomy time: bleeding rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191016045130N1**

Registration date: **2019-11-15, 1398/08/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-15, 1398/08/24**

Update count: **0**

Registration date

2019-11-15, 1398/08/24

Registrant information

Name

Parisa Naviyafar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 7543

Email address

naviyafar.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Outcomes and Complications of Two transection techniques (Crush-Clamp versus Ultrasonic Dissection) for Hepatic resection in Patients with Hepatic Mass

Public title

Comparison of the Outcomes and Complications of Two transection techniques (Crush-Clamp versus Ultrasonic Dissection) for Hepatic resection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are supposed to be hepatectomy

Exclusion criteria:

Patient dissatisfaction

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were randomly divided into two groups according to the Random permutations method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the data analyzer are not aware of the techniques of surgery.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.AJUMS.REC.1398.268

Health conditions studied**1****Description of health condition studied**

Hepatic failure

ICD-10 code

K72

ICD-10 code description

Hepatic failure, not elsewhere classified

Primary outcomes**1****Description**

Operation time

Timepoint

In operation

Method of measurement

By watch

2**Description**

Hepatectomy time

Timepoint

In operation

Method of measurement

By watch

3**Description**

Bleeding rate

Timepoint

In operation

Method of measurement

By measuring the suction

Secondary outcomes**1****Description**

ABG changes

Timepoint

During and after surgery

Method of measurement

Laboratory test

2**Description**

Urine output

Timepoint

During and after surgery

Method of measurement

By checking the urine bag

3**Description**

Liver enzymes profile

Timepoint

2, 3 and 5 day after surgery

Method of measurement

Laboratory test

4**Description**

Patient INR

Timepoint

1, 2, 3 and 4 day after surgery

Method of measurement

Laboratory test

Intervention groups**1****Description**

Intervention group: Patients will undergo a hepatectomy by ultrasonic incision.

Category

Treatment - Surgery

2**Description**

Control group: Patients will undergo a hepatectomy by crush- clamp.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Meisam Moezzi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor in Research Affairs, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Grant name**Grant code / Reference number**

U-98060

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor in Research Affairs, Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Parisa Naviyafar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Associate professor

Latest degree

Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available