

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of sonography and laparoscopy for diagnosis of intraabdominal bleeding and organ injury in patients suffering from thoracoabdominal stab wound

Protocol summary

Study aim

Comparison of the results of sonography and laparoscopy in the diagnosis of intraabdominal hemorrhage and abdominal visceral injury in patients suffering from thoracoabdominal stab wound. To find the safety and efficacy of FAST as a noninvasive and safe diagnostic method for evaluating diaphragmatic injury in these patients, which reduces the cost of treatment and the time of admission.

Design

An open-label, single arm, and single-center clinical trial on 30 patients.

Settings and conduct

A chest CT scan is done for all studied patients in the emergency department of the Besat hospital, Hamadan, Iran. In patients with the evidence of haemothorax and/or pneumothorax in chest CT scan, a FAST is performed. Then, the patients undergo a diagnostic laparoscopy. under general anesthesia in the operating room. The results of ultrasonography for trauma are compared by comparing the results of diagnostic laparoscopy. If any of the results of the aforementioned diagnostic methods is positive, the patient will be the candidate for the laparotomy to determine the cause and treatment of bleeding and diaphragmatic injury.

Participants/Inclusion and exclusion criteria

Inclusion: patients with thoracoabdominal stab wound and the evidence of hemothorax and/or pneumothorax in chest CT scan. Exclusion: unstable patients, patients with stab wound in areas other than the thoracoabdominal space, patients with past medical history of COPD or heart failure

Intervention groups

All patients undergo FAST and diagnostic laparoscopy for diagnosis of diaphragmatic injury.

Main outcome variables

FAST results; laparoscopy results; hospital days,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181201041808N1**

Registration date: **2019-03-04, 1397/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-04, 1397/12/13**

Update count: **0**

Registration date

2019-03-04, 1397/12/13

Registrant information

Name

Amir Kasraianfard

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

2018-06-10, 1397/03/20

Actual recruitment end date

2019-06-20, 1398/03/30

Trial completion date

2018-12-21, 1397/09/30

Scientific title

Comparison of sonography and laparoscopy for diagnosis of intraabdominal bleeding and organ injury in patients suffering from thoracoabdominal stab wound

Public title

Comparison of sonography and laparoscopy for diagnosis of intraabdominal bleeding and organ injury in patients suffering from thoracoabdominal stab wound

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients suffering from stab wound in the thoracoabdominal area defined as the space between 4th intercostal space anteriorly, 6th intercostal space laterally, 8th intercostal posteriorly and the lower edge of the ribs inferiorly. Patients with hemothorax and/or pneumothorax visible in the chest computed tomography scan.

Exclusion criteria:

Unstable patients Patients with history of diaphragmatic injury which has not been treated. Patients with stab wound in areas other than the thoracoabdominal area Patients with no evidence of hemothorax or pneumothorax in chest CT scan Patients with past medical history of COPD or heart failure

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **29**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamedan University of Medical Sciences

Street address

Ethics Committee in Research, Faculty of Research & Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd, Hamadan

City

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Province

Hamadan

Postal code

6517838736

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.UMSHA.REC.1397.169

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

Comparison of sonography and laparoscopy for the diagnosis of intra abdominal bleeding and abdominal visceral injury

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Free fluid in the abdomen - Abdominal visceral injury - Diaphragmatic injury

Timepoint

Early after stab wound

Method of measurement

Focused assessment with sonography for trauma - Laparoscopy

Secondary outcomes

empty

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

Intervention group: FAST and laparoscopy- FAST: using the Probe of the Affiniti 50 ultrasound device manufactured by the Phillips Netherlands - Viewing the Morrison (between the liver and the right kidney), splenorenal (between the spleen and the left kidney) and the pelvis spaces for free fluid- Laparoscopy: diagnostic laparoscopy with Karl Storz Laparoscopy Made in Germany - Installing a 15mm port under the umbilical cord and inserting the camera through this port, and fully observing the abdominal spaces and organs and diaphragms

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Amir Kasraianfard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Vice Chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shaheed
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Amir Kasraianfard

Position

resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable