Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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
Hamadan

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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Shahid Beheshti Blvd, Hamadan

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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 fahmideh Blvd., Hamadan, Iran

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Vc_research@umsha.ac.ir

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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