

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Novel Minimally Invasive Approach for Anterior Pelvic Ring Fracture Fixation in Patients with Pelvic Fracture

Protocol Summary

Study Aim

introduce the MIAPF as a situated approach for ant pelvic ring fractures

Design

a clinical trial which has control group and parallel groups without blindness.

Settings and Conduct

In our study, 18 patients who referred to Akhtar Hospital from 2016 to 2019. The MIAPF started with a transversely 1 inch-long incision over the pubic symphysis. With the intact abdominal rectus muscle, the position and path of screw was defined and optimized with a 2.7 mm drill bit with the help of C-ARM fluoroscopic 2D images. A 3-hole reconstruction plate was fixed in the pubic body of the intact side with two 3.5 mm cortical screws. Then a long cortical screw (Synthes, Switzerland) was placed in the fracture site according to the previously-planned path with drill bit. The length of the screws varied from 80 to 120 mm, depending on the anatomy of the patient's pelvis. If bilateral anterior pelvic fracture was present, then two long cortical screws (Synthes, Switzerland) were placed in bilateral fracture sites. After placing the screws and plate, a C-ARM fluoroscopy was again used to verify the position of plate and appropriate length of the screws.

Participants/Inclusion and Exclusion Criteria

Inclusion: patients with ant pelvic ring fractures that are nearby the symphysis nakatani classification type 1
Exclusion: fractures away from pubic symphysis or nakatani classification type 2 or 3 patients do not accept this method

Intervention Groups

all patients who referred to Akhtar Hospital with ant pelvic ring fractures that were nearby the pubic symphysis from 21.3.2015 control: patients do not accept this procedure and treated with previous method

Main Outcome Variables

time of surgery . blood loss. infection rate

General Information

Reason for Update

Acronym

MIAPF

IRCT Registration Information

IRCT registration number: **IRCT20191210045682N1**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

Registration Date

2020-04-09, 1399/01/21

Registrant Information

Name

aliasghar alamian

Name of Organization / Entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8803 1255

Email Address

shahramalamian@gmail.com

Recruitment Status

Recruitment complete

Funding Source

Expected Recruitment Start Date

2015-03-21, 1394/01/01

Expected Recruitment End Date

2019-12-21, 1398/09/30

Actual Recruitment Start Date

2015-03-30, 1394/01/10

Actual Recruitment End Date

2019-12-21, 1398/09/30

Trial Completion Date

2019-12-21, 1398/09/30

Scientific title

A Novel Minimally Invasive Approach for Anterior Pelvic Ring fracture Fixation in patients with pelvic fracture

Public title

a less invasive surgery for pelvic fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

pelvic fracture which is nearby the symphysis fractures that include classification nakatani type 1

Exclusion criteria:

fractures which are nakatani type 2 or 3 patient dosent accept this surgery fractures with comminution of ramus that cant be fixed with this procedure

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **18**

Actual sample size reached: **18**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

low blood loss - minor incision- better recovery- low pain after surgery

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of shahid beheshti university of medical science

Street address

sheykh bahaie. ghavam pour.

City

tehran

Province

Tehran

Postal code

1995758464

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

ir.sbm. msp.rec.1397.799

Health conditions studied

1

Description of health condition studied

anterior pelvic ring fracture

ICD-10 code

M00-M99

ICD-10 code description

Biomechanical lesions, not elsewhere classified, Pyogenic arthritis

Primary outcomes

1

Description

bleeding amount in this method.

Timepoint

during surgery

Method of measurement

volume of suction& number of strile gauze

2

Description

infection rate after surgery

Timepoint

after 1and 2 week.3month. 1year

Method of measurement

physical exam

3

Description

duration time of surgery.

Timepoint

during surgery

Method of measurement

record by surgery nurse

Secondary outcomes

1

Description

a smaller incision

Timepoint

during surgery

Method of measurement

ruller

2

Description

lower pain

Timepoint

just after surgery 1.2 weeks after that

Method of measurement

patients scoring 1 to 10

Intervention groups

1

Description

Intervention group: patients who were referred to Akhtar hospital with ant. pelvic ring fx. in our study: Under general or local anesthesia, patients were positioned on a radio-transparent operation table in the supine position. Preparation and drape of the skin was from above the umbilicus to the upper third of the lower extremities. The MIAPF started with a transversely 1-inch-long incision over the pubic symphysis. With the intact abdominal rectus muscle, the position and path of screw was defined and optimized with a 2.7 mm drill bit with the help of C-ARM fluoroscopic 2D images. A 3-hole reconstruction plate was fixed in the pubis body of the intact side with two 3.5 mm cortical screws. Then a long cortical screw (Synthes, Switzerland) was placed in the fracture site according to the previously-planned path with drill bit. The length of the screws varied from 80 to 120 mm, depending on the anatomy of the patient's pelvis. If bilateral anterior pelvic fracture was present, then two long cortical screws (Synthes, Switzerland) were placed in bilateral fracture sites through three-hole reconstruction plate.

Category

Treatment - Surgery

2

Description

Control group: control group was the patients who do not accept this technique and treated with previous procedures. The fan incision & fixation with bigger plate and screw

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

akhtar hospital

Full name of responsible person

ali asghar alamian

Street address

shariaty blvd. sharifi manesh ave. azar street

City

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199565458464

Phone

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Fax

Email

shahramalamian@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

akhtar bone and joint research center

Full name of responsible person

seyyed mohammad qoreishy

Street address

sharifimanesh ave

City

tehran

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199545688464

Phone

+98 21 2664 0307

Email

shahramalamian@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

akhtar hospital

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

seyyed mohammad qoreishy

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
orthopaedic student
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

bleeding. time of surgery. complication of surgery

When the data will become available and for how long

any time

To whom data/document is available

orthopaedic student. orthopaedic surgeon

Under which criteria data/document could be used

to compare with other method of surgery of pelvic ring fx

From where data/document is obtainable

by Email from ali asghar alamian or seyyed mohammad qoerishy

What processes are involved for a request to access data/document

email or phone call

Comments