

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Compared celox with using a compression bandage and compression bandage alone at time of bleeding control in patients with penetrating wounds of the extremities

#### Protocol summary

##### Summary

In this randomized clinical trial on patients with penetrating trauma will be done during the study period, patients with penetrating wounds from knives, glass and car accidents with intentional or unintentional mechanism of injury to Imam Hossein hospital will be divided into experimental and control conditions. Inclusion criterias in the study were penetrating wounds in the extremities, aged 18 to 50 years, and lesion with length greater than 3 cm and less than 15 cm. Celox to the extent required in the experimental group and the control group plus pressure dressing will be used to stop bleeding. Duration of time to bleeding control will be recorded. In order to measure of the amounts of bleeding after treatment, 10 × 10 eight layers of celox gases that are used to control bleeding counts, blood-stained gas equivalent to 20 cc of blood are considered. Other variables such as demographic data and vital signs, methods and extent of hydration of patients in both groups will be determine.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104206238N1**  
Registration date: **2014-04-15, 1393/01/26**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-04-15, 1393/01/26

##### Registrant information

##### Name

Hamid Reza Hatamabadi

##### Name of organization / entity

Shahid Beheshti University of edical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 73430

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor forr Research of Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2014-03-13, 1392/12/22

##### Expected recruitment end date

2014-08-01, 1393/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Compared celox with using a compression bandage and compression bandage alone at time of bleeding control in patients with penetrating wounds of the extremities

##### Public title

Compared celox with pressure bandages at time of bleeding control in penetrating extremity wounds

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1-Penetrating wounds in extrimities with sharp objects and accidental or non accidental mechanism of injury. 2- Age 18 to 50 years 3- Length of

lesion greater than 3 cm and less than 15 cm. Exclusion criteria: 1- Foreign body in ulcer 2- There are coagulation defects and anticoagulation drugs 3- The patient has hypovolemic shock 4- The same material used to control clotting 5 - The patients needs to receive blood or blood products

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Scinces

**Street address**

Tabnank St, Yaman St, Shahid Chamran highway

**City**

Tehran

**Postal code**

1985717443

**Approval date**

2012-07-08, 1391/04/18

**Ethics committee reference number**

121

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

Open wound of upper and lower extrimity

**ICD-10 code**

T11/1-T13/

**ICD-10 code description**

open wound of upper and lower extrimity

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

Time to achieve control of bleeding

**Timepoint**

5 min and 10 min

**Method of measurement**

hour

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

Bleeding volume

**Timepoint**

5 min and 10 min

**Method of measurement**

Numbers dipped in blood gas celox

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

compression bandage gases typical 10 × 10 eight layers after 5 and 10 minutes were reviewed and any gas-blood equivalent to 20 cc of blood

**Category**

Treatment - Other

**2****Description**

compression bandage gases typical 10 × 10 eight layers after 5 and 10 minutes were reviewed and any gas-blood equivalent to 20 cc of blood and

**Category**

Treatment - Drugs

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

Imam Hossein hospital

**Full name of responsible person**

Hamid Reza Hatamabadi

**Street address**

Shahid Madani St, Immam Hosein hospital,

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Vice-chancellor for research of Shahid Beheshti  
University of Medical Sciences

**Full name of responsible person**

Hamid Reza hatamabadi

**Street address**

Tabnak St, Yaman St, Shahid Chamran highway  
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**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for research of Shahid Beheshti  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

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

*empty*

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hamid Reza Hatamabadi

**Position**

Emergency Medicine, Associate Professor

**Other areas of specialty/work****Street address**

Emergency Medicine, Emam Hossein Hospital, Shahid  
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**Position**

Emergency Medicine, Associate Professor

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*