# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Explaining “OrameHarreRiyavi”(acute pulmonary edema) and investigating the effect of Hijamat (wet cupping therapy) on acute inhalant intoxication with chlorine gas

## Protocol summary

**Study aim**
Investigating the effect of “Hijamat” on acute inhalant intoxication with chlorine gas

**Design**
Quasi-experimental clinical trial with the sample of 60 individuals and a simple random allocation method will be used to assign participants to the experimental and control groups

**Settings and conduct**
Sampling will be done from patients with inhalant intoxication referring to the Intoxication Emergency Department of Loghman Hospital. After performing the necessary new medicine treatments and obtaining consent and randomization,“Hijamat” will be used as a treatment for the intervention group,only once at the patient’s visit, however the evaluation of patients in both groups will be measured and recorded in three stages, one hour, one week and one month after the intervention.Patients’ signs and symptoms will be investigated and registered through questionnaires, instrumental measurements and examination by three separate physicians, in both groups. Finally, the data will be analyzed using statistical software.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Moderate to severe intoxication. Age: 2 - 60 years old. Consent to Hijamat. No history of previous pulmonary diseases or hypersensitivity syndromes Not taking any anticoagulants drugs Not consuming foods such as egg, fish, liver, pickle and dairy products during the last 12 hours. No having sex, menstruation, severe bleeding or any kind of bleeding within the last 12 hours. Exclusion criteria: Not having consent to do Hijamat. No diseases with pulmonary symptoms during the Evaluation period. Unwillingness to cooperate in the post-intervention assessment.

**Intervention groups**
Inhalant intoxicated patients with chlorine gas

**Main outcome variables**
Dyspnea, maximum exhale respiratory flow, blood oxygen saturation level, PR , RR and BP, pulmonary'sounds and other organs signs and symptoms

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20200309046727N1**
Registration date: **2020-12-13, 1399/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-13, 1399/09/23**
Update count: **0**

**Registration date**
2020-12-13, 1399/09/23

**Registrant information**

**Name**
Khatereh Akbarimashak
**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**
2020-11-21, 1399/09/01

**Expected recruitment end date**
2021-09-21, 1400/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Explaining “OrameHarreRiyavi”(acute pulmonary edema) and investigating the effect of Hijamat (wet cupping therapy) on acute inhalant intoxication with chlorine gas

**Public title**

Investigating the effect of Hijamat (wet cupping therapy) on acute pulmonary edema due to acute inhalant intoxication with chlorine gas

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Moderate to severe inhalant intoxication with bleaching agent Age between 2 to 60 years old Consent to Hijamat (wet cupping therapy)

**Exclusion criteria:**

Existence of history of previous lung disease such as asthma and chronic obstructive pulmonary disease (COPD) Existence of history of hypersensitivity syndrome such as urticaria, atopic dermatitis (eczema) Having sex or menstruation, severe bleeding and any kind of bleeding within the last 12 hours Consuming foods such as egg, fish, liver, pickle and dairy products during the last 12 hours Presence of any acute or chronic illnesses in active phase Taking any anticoagulants drugs such as Aspirin, Warfarin, Plavix and Osvix

**Age**

From **2 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study,a simple random allocation method using Random Allocation Software (http://mahmoodsaghaie.tripod.com/softwares/randalloc.html) will be used to assign participants to the experimental and control groups.It will be done until reaching the desired sample size in each group(30 people).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Because of ethical considerations, this study is a quasi-experimental study, and the conditions, severity and method of intoxication cannot be controlled in advance

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of shahedUniversity

**Street address**

No. 364, Azadi residential complex, ETKA Alley, ShahidJavadAkbari Blvd., AzadiStreet, Tarasht

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1458814376

**Approval date**

2020-02-17, 1398/11/28

**Ethics committee reference number**

IR.SHAHED.REC.1398.130

## Health conditions studied

### 1

**Description of health condition studied**

Acute Respiratory Distress Syndrome caused by chlorine gas inhalation

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Maximum respiratory flow

**Timepoint**

Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)

**Method of measurement**

Peak flow meter device

### 2

**Description**

The level of oxygen saturation of peripheral blood

**Timepoint**

Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)

**Method of measurement**

Pulse Oximeter device

**3**

**Description**
Respiratory Sounds (wheezes and crackles (rales))
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
Lung sound examination with stethoscope

**4**

**Description**
Respiratory rate
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
Examination and counting per minutes

**5**

**Description**
Puls rate
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
Examination and counting per minutes

**6**

**Description**
blood pressure
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
Mercury sphygmomanometer device

**7**

**Description**
Gastrointestinal symptoms
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
Questionnaire

**8**

**Description**
Skin and mucosal irritation symptoms
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
Questionnaire

**9**

**Description**
Neurological and cognitive symptoms
**Timepoint**
Before Hijamat (wet cupping therapy), and one hour, one week and one month after Hijamat (wet cupping therapy)
**Method of measurement**
questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: they receive Hijamat (wet cupping therapy) once between two scapulae, immediately after patient’s visit and after receiving allopathic medical treatment, with the use of a disposable cup for Hijamat (wet cupping therapy) and manual suction for 3 to 5 minutes and creating 10 millimeter skin scratches with a 15 bistoury blade, and then repeating the suction and taking 30 cc blood sampling. Then evaluating the patient’s symptoms 3 times in one hour, one week and one month after Hijamat (wet cupping therapy).
**Category**
Treatment - Other

**2**

**Description**
Control group: only receive allopathic medicine treatments at the beginning of the visit and then the evaluating of the patient's symptoms within one hour and one week and one month after the visit.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Loghman e Hakim hospital
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**
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Shahed University
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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**
Shahed University
**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**
Shahed University
**Full name of responsible person**
KhaterehAkbariMashak
**Position**
Resident
**Latest degree**
Medical doctor
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**

Kh.akbari92@gmail.com

## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The study is still undergoing

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available