

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation Of Clinical And Peak Flow Metric Effect Of Intravenous Glucagon On Treatment Of Acute Severe Asthma Attack

#### Protocol summary

##### Study aim

This study is aimed to evaluate the effect of glucagon on the treatment of severe asthma attack.

##### Design

20 patients, 18 to 55 years, presenting to ED with asthma attack will be evaluated by physician. Their clinical status, vital sign, blood glucose, PEFr and FEV1 will be recorded. Patients who meet the inclusion criteria will be enrolled the study. All patients will receive the standard treatment of severe asthma attack (5 mg nebulized albuterol every 20 minutes for 3 doses, 0.5 mg ipratropium every 20 minutes for 3 doses, 50 mg oral prednisolone). Patients will be randomly assigned to either intravenous glucagon or a placebo medication (according to random number table).

##### Settings and conduct

All patients presenting to ED with asthma attack, considering the inclusion and exclusion criteria and in case of severe attack, in addition to the standard treatment, will randomly receive either 1 mg intravenous glucagon or its equivalent of normal saline. physicians evaluating cases, nurses injecting medication and patients do not know if patients are receiving glucagon or placebo; the medication is prepared by the fourth person. Spirometry will be repeated at 10, 15, 30, 45 and 60 minutes after injection. Blood glucose will be measured again at 20 minutes after intervention. All subjects will be reevaluated clinically after one hour. Ultimately all data gathered will be analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: severe asthma attack, age between 18 and 55 Exclusion criteria: History of diabetes mellitus, smoking, ischemic heart disease, emphysema or chronic bronchitis, insulinoma, pheochromocytoma, current oral or injectable corticosteroids, pregnancy, lactation, need for intubation.

##### Intervention groups

All patients with severe asthma attack will receive the standard treatment (5 mg nebulized albuterol every 20

minutes for 3 doses, 0.5 mg ipratropium every 20 minutes for 3 doses, 50 mg oral prednisolone). In addition to the standard treatment, patients will randomly receive either 1 mg intravenous glucagon or its equivalent of normal saline.

##### Main outcome variables

PEFR; FEV1

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131118015446N13**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

##### Registration date

2018-02-17, 1396/11/28

##### Registrant information

##### Name

Hassan Motamed

##### Name of organization / entity

Emergency Department, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3079

##### Email address

motamed-h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University Of Medical Science

**Expected recruitment start date**

2017-10-23, 1396/08/01

**Expected recruitment end date**

2018-10-23, 1397/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation Of Clinical And Peak Flow Metric Effect Of Intravenous Glucagon On Treatment Of Acute Severe Asthma Attack

**Public title**

Effect Of Glucagon on Treatment Of Acute Severe Asthma Attack

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Severe asthma attack Age between 18 and 55

**Exclusion criteria:**

History of diabetes mellitus Smoking Ischemic heart disease Emphysema or chronic bronchitis Insulinoma pheochromocytoma Current oral or injectable corticosteroids, pregnancy Pregnancy Lactation Need for intubation

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Table of random numbers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients know they are participating in a study that is aimed to evaluate the effect of glucagon on the treatment of severe asthma attack but they are not informed that they receive placebo or glucagon The physician who evaluates the clinical status of patients and the nurse who injects the drug are not aware of the medication that patients receive.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Science

**Street address**

Ahvaz Jundishapur University Of Medical Science, Golestan Highway, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Approval date**

2017-09-26, 1396/07/04

**Ethics committee reference number**

IR.AJUMS.REC.1396.474

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

Asthma

**ICD-10 code**

J45

**ICD-10 code description**

Asthma

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

Peak Expiratory Flow Rate (PEFR)

**Timepoint**

At 0, 10, 15, 30, 45 ,60 minutes after intervention

**Method of measurement**

Litre/minute, by spirometry

**2****Description**

FEV1

**Timepoint**

At 0, 10, 15, 30, 45 ,60 minutes after intervention

**Method of measurement**

Litre, by spirometry

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

Respiratory rate

**Timepoint**

At 0 and 60 minutes after intervention

**Method of measurement**

Counting of respiration in one minute

**2**

**Description**

Pulse rate

**Timepoint**

At 0 and 60 minutes after intervention

**Method of measurement**

Counting of pulse in one minute

**3**

**Description**

Blood pressure

**Timepoint**

At 0 and 60 minutes after intervention

**Method of measurement**

mmHg, by sphygmomanometer

**4**

**Description**

Blood glucose

**Timepoint**

At 0 and 20 minutes after intervention

**Method of measurement**

mg/dL, by glucometer

**5**

**Description**

blood oxygen saturation levels (SpO<sub>2</sub>)

**Timepoint**

At 0 and 60 minutes after intervention

**Method of measurement**

Percentage, by pulse oximeter

**Intervention groups**

**1**

**Description**

Intravenous injection of 1 mg of glucagon over 1minute for case group

**Category**

Treatment - Drugs

**2**

**Description**

Intravenous injection of 1 mL normal saline for control group

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Golestan hospital

**Full name of responsible person**

Dr Hassan Motamed

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**2**

**Recruitment center**

**Name of recruitment center**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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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**  
Ahvaz Jundishapur University Of Medical Science  
**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

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Ahvaz Jundishapur University Of Medical Science  
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**Position**  
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## Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be 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

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

**Analytic Code**

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

**Data Dictionary**

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