Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 recieving 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

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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
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Ahvaz
Province
Khouzestan
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 (SpO2)

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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Sponsors / Funding sources

1

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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
Name of organization / entity
Ahvaz Jundishapur University Of Medical Science
Full name of responsible person
Dr Hassan Motamed
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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