

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluating the Effects of Inhaled Corticosteroid on Insulin Sensitivity in Asthmatic Patient

#### Protocol summary

##### Summary

Asthma is an inflammatory disease, which causes air flow limitation and increase insulin resistance. The present study will carry out in order to investigate insulin resistance and the effect of inhaled corticosteroid (ICS) on insulin resistance in asthmatic patients. The patients with age over 15 years, stage2 or 3 asthma, FEV1 above 60%, no previous use of oral or inhaled corticosteroid and no history of diabetes will participate in this interventional, quasi-experimental study and patients with history of diabetes or malignancy, pregnancy, acute infection, endocrine disorder, taking any medication that affects glucose metabolism, obesity (defined by BMI $\geq$ 30 kg/m<sup>2</sup>) and sleep apnea excluded. Spirometry, fasting blood sugar, BS2HPP, HbA1C, LDL, HDL, Insulin Level, and CRP will measure both at the base line and after two months of treatment. Then impaired fasting glucose (IFG) will examine, and HOMA-IR will calculate. patients will receive symbicort inhaler with dose 320 microgram every 12h for two months.

#### General information

##### Acronym

Effects of Inhaled Corticosteroid on Insulin Sensitivity

##### IRCT registration information

IRCT registration number: **IRCT201605247411N2**

Registration date: **2016-06-27, 1395/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-27, 1395/04/07

##### Registrant information

###### Name

Hanieh Raji

##### Name of organization / entity

Imam Khomeini hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3221 6501

##### Email address

raji-h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2014-07-02, 1393/04/11

##### Expected recruitment end date

2015-10-31, 1394/08/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the Effects of Inhaled Corticosteroid on Insulin Sensitivity in Asthmatic Patient

##### Public title

Does inhaled corticosteroid predispose asthmatic patients to diabetes?

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria included: age over 15 years; stage2 or 3 asthma; FEV1 above 60%; no previous use of oral or inhaled corticosteroid and no history of diabetes.

Exclusion criteria included: history of diabetes or malignancy; pregnancy; acute infection; endocrine disorder; taking any medication that affects glucose metabolism; obesity (defined by BMI $\geq$ 30 kg/m<sup>2</sup>) and

sleep apnea

#### Age

No age limit

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 28

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz Jundishaur university of medical sciences

##### Street address

Ahvaz University of Sciences, Golestan street, Ahvaz,  
Iran

##### City

Ahvaz

##### Postal code

Iran

#### Approval date

2011-11-19, 1390/08/28

#### Ethics committee reference number

ETH-288

## Health conditions studied

### 1

#### Description of health condition studied

Chronic lower respiratory diseases

#### ICD-10 code

J45

#### ICD-10 code description

Asthma

## Primary outcomes

### 1

#### Description

FBs, BS2HPP, HbA1C, LDL, HDL, Insulin Level, CRP and HOMA-IR

#### Timepoint

at the beging of study and two months later

#### Method of measurement

examination

## Secondary outcomes

### 1

#### Description

FEV1, FVC, FEV1/FVC

#### Timepoint

At the beginning of study and two months later

#### Method of measurement

Spirometry device

## Intervention groups

### 1

#### Description

Inhaled corticosteroid

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini

##### Full name of responsible person

##### Street address

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Science

##### Full name of responsible person

Seyed Behzad Makhmalzadeh

##### Street address

Ahvaz Jundishapur University of Sciences

##### City

Ahvaz

#### 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***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****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Seyed Hamid Borsi

**Position**

Assistant 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*