

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/m²) 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)

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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/m²) 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

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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*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**

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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*