

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effects of inhalational steroids on hypopituitary adrenal gland

Protocol summary

Summary

The aim of this study was to assess the effects of high dose inhalational steroids on hypopituitary adrenal axis. 62 moderate asthmatic patients aged 15-65 years and without history of smoking, occupational asthma or history of systemic steroid consumption within the last 6 months were divided in two equal groups of 31 patients to receive Beclomethasone forte, 250 microgram, 6 puffs per day (1500 microgam/day) or Fluticasone 250 microgram, 6 puffs per day (1500 microgram/day). Patients who received Beclomethasone or Fluticasone previously entered to the same group. Fasting Blood sugar (FBS), spirometry and serum cortisol levels at 0, 30, and 60 minutes following ACTH stimulation injection were measured in all patients. Patients continued to receive previous asthma medications without changing the dose except for steroid MDI dose increased to 2 puffs three times daily for three weeks using spacer. FBS, spirometry and cortisol levels at 0, 30, and 60 minutes following ACTH stimulation test were measured at the first day and after three weeks. If the patient consumed systemic steroid or did not follow advised dose during three weeks, was excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712121731N1**
Registration date: **2009-07-22, 1388/04/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-07-22, 1388/04/31

Registrant information

Name

Keivan Gohari Moghadam

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Endocrine and Metabolism Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2009-04-09, 1388/01/20

Expected recruitment end date

2010-07-11, 1389/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of inhalational steroids on hypopituitary adrenal gland

Public title

Effects of High dose Fluticasone and Beclomethasone on hypopituitary adrenal axis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of moderate asthma

Exclusion criteria: cigarette smoking, occupational asthma, history of systemic steroid use during the last 6 months, low compliance for 1500 microgram MDI use, consumption of systemic steroid during the study

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **62****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

ACTH stimulation test and measurement of serum cortisol levels following it and increased steroid MDI dose and repeat stimulation test and cortisol measurement are the features of the study which is much more precise for adequacy of adrenal-hypopituitary axis.

Secondary Ids

empty

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

Endocrine Research Center

Street address

Shariati Hospital

City

Tehran

Postal code

1411413137

Approval date

empty

Ethics committee reference number

E0026

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

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

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

Serum cortisol levels

Timepoint

0, 30, and 60 min. after ACTH in the 1st and last session after (3 weeks)

Method of measurement

Serum Cortisol levels

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

FBS

Timepoint

First and 3 weeks 3 after increased MDI dose

Method of measurement

Serum glucose fasting level

2**Description**

Spirometric values

Timepoint

3 weeks later

Method of measurement

Spirometry

Intervention groups**1****Description**

Beclomethasone 250 microgram MDI to 6 puffs /d (1500 microgram) for 3 weeks by spacer.

Category

Treatment - Drugs

2**Description**

Fluticasone MDI 250 microgram to 6 puffs/d (1500 microgram) for 3 weeks by spacer

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shariati hospital, Tehran University of Medical Sciences

Full name of responsible person

Keivan Gohari Moghadam

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Shariati Hospital, North Kargar Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrine Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Heshmat

Street address

Shariati Hospital

City

Tehran

Grant name**Grant code / Reference number**

P.M .8611/82

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Endocrine Research Center, Tehran University of Medical Sciences

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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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