

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The comparison between Budsonide and Fluticasone Propionate in asthma control of under 6 year old patients with asthma

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of effectiveness of fluticasone propionate and budesonide on asthma control test among under 6 yrs old children

Last update: **2019-02-01, 1397/11/12**

Update count: **0**

Registration date

2019-02-01, 1397/11/12

Design

Children was randomly divided in two groups. One group receive FP 250 mcg BD (group1)and another group receive Budesonide 400 mcg BD (group2)after discharge and then F/U monthly for 3 months. Symptoms at night and day, salbutamole requirements and the score of asthma control was measured monthly in two group and will compare at the end of study

Registrant information

Name

Akefeh Ahmadiafshar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 1422 3095

Email address

akefeh45@zums.ac.ir

Settings and conduct

This study was open label and children after giving writing consent and instructed to use the drug were required to study and will follow for a period of 3 months

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children with ages under 6 yrs old who hospitalized with asthma attack and Receiving B agonist at east two months before admission Exclusion criteria:- having other respiratory anomaly, CF, CDH or neuro muscular disorder _ Not having regular follow up Changing treatment protocol or do not using proper medication during study

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-04-22, 1398/02/02

Intervention groups

Children was randomly divided in two groups. Group1; receive FP 250 mcg BD and group2; receive Budesonide 400 mcg BD after discharge and then F/U monthly for 3 months

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Asthma control test score

Trial completion date

empty

General information

Scientific title

The comparison between Budsonide and Fluticasone Propionate in asthma control of under 6 year old patients with asthma

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100104002976N4**

Registration date: **2019-02-01, 1397/11/12**

Public title

Comparison the effectiveness of budesonide and fluticasone propionate on asthma control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with asthma attack who hospitalized in pediatric ward Didn't receive regular and certain spray before that asthma confirmed by physician

Exclusion criteria:

Having other respiratory anomaly, Cyclic fibrosis, Congenital heart defect and neuro-muscular disorders Changing the prescribed drug don't have regular follow up

Age

From **6 months** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Children randomly receive fluticasone propionate 250 mcg BD or Budesonid 400mcg BD after discharge and follow for 4 months

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanzan University of Medical Sciences

Street address

Azadi Avenu, Zanzan University of Medical Sciences

City

Zanzan

Province

Zanzan

Postal code

4515613191

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

1397.315IR.ZUMS.REC

Health conditions studied

1

Description of health condition studied

Comparison the effectiveness of drugs in asthma controle

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma control score

Timepoint

At the period of 4 months patients investigate monthly

Method of measurement

Asthma control test check list and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: receiving Fluticasone propionate (Flohale125). (Cipla, India) 250 mcg or 2 puff BD

Category

Treatment - Drugs

2

Description

Intervention group2: receiving Budesonid (Budecort 200), (Cipla, India) 400mcg or 2 puff BD at the beginning of study and followed for 3 months .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Akefeh Ahmadaiafshar

Street address

Gavazang Road

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 24 3313 1329

Fax

+98 24 3313 1328

Email

akefeh45@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

Street address

Azadi Blvd

City

Zanjan

Province

Zanjan

Postal code

45139-56183

Phone

+98 24 3315 6393

Email

shoghli@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

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

Zanjan University of Medical Sciences

Full name of responsible person

Akefeh Ahmadiafshar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

Street address

Gavazang Road, Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 1327

Fax

+98 24 3313 1340

Email

akefeh45@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Akefeh Ahmadiafshar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

Street address

Mousavi Hospital, Gavazang Road

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 1329

Fax

+98 24 3313 1340

Email

akefeh45@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Akefeh Ahmadiafshar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Mousavi Hospital, Gavazang Road

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 1329

Email

akefeh45@zums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

In this study the personal address of participants were secured and only the results will be shared

When the data will become available and for how long

After ending and if participants will be consent

To whom data/document is available

The researchers and colleagues who have similar study or interested to it

Under which criteria data/document could be used

Meta analysis or cohort studies have permission to access our data

From where data/document is obtainable

With Email address: akefeh45@zums.ac.ir or zu_afshar@yahoo.com and researchgate or linkedin

What processes are involved for a request to access data/document

1-3 weeks on the basis of my free times might be take to response to request and After getting permission from zanzan University of Medical Sciences . sending is also private

Comments