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

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

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

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

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

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

Main outcome variables
Asthma control test score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100104002976N4**
Registration date: **2019-02-01, 1397/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-01, 1397/11/12**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2019-04-22, 1398/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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, Cyctic fibrosis, Congenital hart 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 propionat 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 Zanjan University of Medical Sciences
Street address
Azadi Avenu, Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
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
Zanjan
Province
Zanjan
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.acir
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 zanjan University of Medical Sciences . sending is also private
Comments