

# Effect of oral azithromycin three times per week on the reduction of asthma exacerbation in patients with persistent asthma

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<b>Registration date</b> 14/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/08/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Asthma is a common lung condition that causes occasional breathing difficulties. It affects people of all ages and often starts in childhood, although it can also develop for the first time in adults. This study evaluated the effect of oral azithromycin on reduction of asthma exacerbations in adults with persistent asthma.

### Who can participate?

Patients aged 12 years or older, with persistent asthma

### What does the study involve?

Participants were either treated as usual or treated as usual with the addition of azithromycin, for 24-weeks.

### What are the possible benefits and risks of participating?

Benefits: Reduced number of exacerbations in the participant.

Risks: Emergence of resistant organisms, adverse effects of Azithromycin may be experienced by the patients

### Where is the study run from?

National Institute of Diseases of the Chest and Hospital (NIDCH), Bangladesh

### When is the study starting and how long is it expected to run for?

June 2018 to June 2019

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Mohammad Ashik Imran Khan  
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# Contact information

## Type(s)

Public

## Contact name

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

15/5/2018/4

# Study information

## Scientific Title

Effect of oral azithromycin three times per week on the reduction of asthma exacerbation in patients with persistent asthma

## Study objectives

Oral azithromycin 500 mg, three times weekly on alternate days as an add on therapy in patients with persistent asthma lead to reduced exacerbations

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 15/05/2018, National Institute of Diseases of the Chest and Hospital (NIDCH) Thesis committee (Mohakhali, Dhaka, 1000, Bangladesh; +880 2-55067131-40; nidch@hospi.dghs.gov.bd), ref: n/a

**Study design**

Single center open label Interventional randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Persistent asthma

**Interventions**

Eligible patients were allocated randomly into group A and in group B in equal number using block randomisation. Group A was treated with azithromycin 500 mg three times every alternate day for 24 weeks and group B was treated with conventional therapy for asthma. The patients of either group were evaluated at baseline, during and at the end of 24 weeks. Records of exacerbation (moderate vs severe), number of exacerbations, symptomatic improvement and adverse events were monitored during the study period.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Azithromycin

**Primary outcome(s)**

Number of asthma exacerbation episodes, measured by self-report at baseline and 24 weeks

**Key secondary outcome(s)**

At 24 weeks:

1. Total number of types of asthma exacerbation according to severity (moderate vs severe)
2. Adverse effects occurring in patients treated with azithromycin
3. Changes in self-reported asthma symptoms

**Completion date**

01/06/2019

**Eligibility****Key inclusion criteria**

1. Aged  $\geq$  12 years
2. Persistent asthma patient

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Substantial parenchymal lung disease, such as emphysema
2. Current and ex-smokers
3. Patients with hearing impairment
4. Abnormally prolonged QTc interval
5. Asthma with bronchiectasis
6. Hypersensitivity to azithromycin

**Date of first enrolment**

01/06/2018

**Date of final enrolment**

01/12/2018

**Locations****Countries of recruitment**

Bangladesh

**Study participating centre**

National Institute of Diseases of the Chest and Hospital (NIDCH)

Mohakahali

Dhaka

Bangladesh

1212

**Sponsor information****Organisation**

National Institute of Diseases of the Chest and Hospital (NIDCH)

**Funder(s)****Funder type**

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			18/08/2022	No	No