ISRCTN14464685 https://doi.org/10.1186/ISRCTN14464685

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

**Submission date**
03/11/2019

**Recruitment status**
No longer recruiting

**Registration date**
14/11/2019

**Overall study status**
Completed

**Last Edited**
18/08/2022

**Condition category**
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

### 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

### Primary study design
Interventional

### Study design
Single center open label Interventional randomized controlled trial

### 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 ≥ 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? |
|---|---|---|---|---|---|
| Protocol file | | | 18/08/2022 | No | No |