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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
03/11/2019		[X] Protocol		
Registration date	Overall study status Completed Condition category Respiratory	Statistical analysis plan		
14/11/2019		Results		
Last Edited		Individual participant data		
18/08/2022		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 ashikmrn@gmail.com

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 ≥ 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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			18/08/2022	No	No