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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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
02/03/2018

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Aged ≥ 12 years
2. Persistent asthma patient

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
160

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)

Sponsor details
Mohakhali
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Sponsor type
Hospital/treatment centre

Website
http://www.nidch.gov.bd

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2019

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