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Assessment and management of children aged 1 - 59 months presenting with wheeze and fast breathing: multicenter study in Pakistan and Thailand

Submission date 27/07/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2004	**Overall study status** Completed	
Last Edited 11/10/2007	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WHO/CAH ID 99025

Study information

Scientific Title

Study objectives
Using current World Health Organization (WHO) guidelines, children with wheezing are being over-prescribed antibiotics and bronchodilators are under utilised. To improve the WHO case management guidelines, more data is needed about the clinical outcome in children with wheezing/pneumonia overlap.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Institutional Review Board (IRB) of Pakistan Institute of Medical Sciences, Islamabad, Pakistan
2. IRB of Queen Sirikit National Institute of Child Health, Bangkok, Thailand
3. World Health Organization (WHO) Ethical Review Committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Wheeze and fast breathing

Interventions
1. Inhaled Salbutamol and reassessment after up to three cycles of bronchodilator therapy repeated at 15 minute interval if necessary
2. Metered Dose Inhaler (MDI) with spacer device

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportions of children aged 1 - 59 months with auscultatory wheeze and fast breathing or lower chest indrawing:
1. Respond to up to three cycles of inhaled salbutamol: response defined as no fast breathing or lower chest indrawing present
2. Fail therapy at day 3 or days 5 - 7 of the initial successful bronchodilator therapy with inhaled salbutamol? Therapy failure defined as:
2.1. Relapse: develop fast breathing or chest indrawing afresh, that does not respond to three cycles of inhaled salbutamol
2.2. Development of any danger sign (except wheezing and fever in young infant)
2.3. Death
2.4. Severe adverse reaction to salbutamol

Secondary outcome measures
In children aged 1 - 59 months with auscultatory wheeze and fast breathing or lower chest indrawing:
1. Proportion with audible wheeze at initial assessment
2. Proportion of responders to up to three cycles of inhaled salbutamol associated with:
2.1. Age
2.2. Respiratory Syncytial Virus (RSV) isolation
2.3. Season
2.4. Number of previous wheezing episodes
2.5. Audible versus auscultatory wheeze
2.6. Family history of asthma
3. Proportion of relapses in children who showed initial improvement associated with:
3.1. Age
3.2. RSV isolation
3.3. Season
3.4. Number of previous wheezing episodes
3.5. Audible versus auscultatory wheeze
3.6. Family history of asthma
4. Received any antibiotic for this or any concurrent illness before follow-up
5. Loss to follow-up
6. Withdrawal of consent

Overall study start date
01/05/2001

Completion date
01/04/2002

Eligibility

Key inclusion criteria
1. Age 1 to 59 months
2. Audible/auscultatory wheeze
3. Respiratory rate above age specific cut off point or lower chest indrawing
4. Classified as no pneumonia with wheeze

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1622

Key exclusion criteria
1. Presence of danger sign:
1.1. Up to two months: stopped feeding well, drowsy, convulsions, stridor in a calm child, fever
1.2. 2 - 59 months: convulsions, clinically severe malnutrition, unable to drink
2. Antibiotics during last 48 hours

Date of first enrolment
01/05/2001

Date of final enrolment
01/04/2002

Locations

Countries of recruitment
Pakistan

Switzerland

Thailand

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

Sponsor details
20, Avenue Appia
Geneva -27
Switzerland
CH 1211

Sponsor type
Research organisation

Website
http://www.who.int/child-adolescent-health/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	Results	01/11/2004	Yes	No