ISRCTN12687253 https://doi.org/10.1186/ISRCTN12687253

Understanding current childhood pneumonia management practices in a few selected low- and middle-income countries

Submission date
23/10/2023

Recruitment status
No longer recruiting

Registration date
27/12/2023

Overall study status
Completed

Last Edited
04/08/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims

Pneumonia is the leading cause of morbidity and mortality in children 1-59 months of age. An estimated 138 million pneumonia episodes occurred in under-five children in 2015. Of these, 16% had chest indrawing pneumonia. Every year, pneumonia causes over 800,000 deaths in under-five children, and the burden is disproportionately borne by children living in sub-Saharan Africa and South Asia. The WHO revised the childhood pneumonia classification in 2013. The revised classification includes only two categories of pneumonia; “pneumonia” with fast breathing and/or lower chest indrawing, which requires outpatient therapy with oral amoxicillin, and “severe pneumonia”, pneumonia with any general danger sign, which requires referral to a hospital for injectable antibiotic treatment. Subsequently, in 2014, the WHO revised its pocketbook and IMCI chart booklet to incorporate the treatment of chest indrawing pneumonia with oral amoxicillin. Since 2014, several countries have adopted the new recommendation to treat children with lower chest indrawing pneumonia with oral amoxicillin on an outpatient basis. In 2018, a retrospective analysis of data from hospitalised children with pneumonia in Kenya showed high mortality among children with mild to moderate palmar pallor, weight-for-age z score (WAZ) less than -3 standard deviation and lower chest indrawing. The authors recommended that these children be treated in a hospital instead of on an outpatient basis as per the current WHO recommendation. A 2-day exploratory meeting of pneumonia research experts was held in WHO, Geneva, in September 2018 to evaluate the implications of this new evidence and other data. The expert panel suggested short-term prospective observational /cohort studies to collect outcome data for children 2–59 months old with lower chest indrawing in real-life settings where the current WHO pneumonia guidelines are being implemented in an outpatient setting. Although 45 countries have revised their national policy to manage children with chest-indrawing pneumonia on an outpatient basis, there is little empirical evidence and experience about its implementation in a programme setting. Thus, it is essential to study this. A prospective observational study will help us gather information from health facilities in some selected countries in various regions concerning the management of children with chest indrawing pneumonia and its outcomes when managed on an outpatient basis.

Who can participate?
Children 2-59 months old with chest-indrawing pneumonia presenting at the participating primary health care facility

What does the study involve?
A prospective observational cohort study will be conducted. The primary objective is to evaluate the survival status (outcome) by day 15 after presentation at a primary health care facility in a programme setting. The secondary objective is to examine survival status and management (including oral treatment, which one, for how many days, or hospitalisation, with injectable antibiotics, how many days, and treatment adherence).

The study will be conducted at the primary care health facility level, where trained healthcare workers are available. The healthcare worker will assess a child with a cough and/or difficulty breathing presenting at the primary care facility. Based on the assessment, the healthcare worker will classify the child into no pneumonia, fast-breathing pneumonia, chest-indrawing pneumonia, severe pneumonia, and manage (treat or refer) according to the national guidelines /policy. The healthcare worker will enter information such as the patient's name, age, address, parents' phone number, clinical assessment, and treatment given into the facility register. Further, the healthcare worker will also take the informed written consent from the parents of all children for the day 15 follow-up.

The research staff will collect the information of all the recruited children from the facility who register daily for follow-up visits. On day 15, the research team member will visit the child's home or hospital to collect information about the vital status of the child and treatment. A total of 310 children 2-59 months of age with chest-indrawing pneumonia will be followed up at each site. Depending on the site, all study data will be collected on paper or an electronic device. Protecting the confidentiality of the data collected in the study will be a high priority. Data will be primarily accessible only to the 'Research Team'. The data/records will be kept for 5 years from the initial assessment date to complete all analyses, and then they will be destroyed.

Data will be analysed using STATA software. Frequencies and percentages will be calculated for categorical variables such as sex, treatment received and vital outcome. At the same time, mean (standard deviation) and median (interquartile range) will be calculated for continuous variables such as age, days of treatment, etc.
However, sites will be finalised in consultation with the WHO regional offices. The study will be conducted in three phases [preparatory phase (duration three months), data collection phase (duration 12 months), and data analysis, report writing and dissemination of results (duration three months)].

What are the possible benefits and risks of participating?
As this study does not provide any intervention, there will be no direct benefit or risk.

Where is the study run from?
The study will be conducted in 6-8 selected countries (a few in Africa, such as Ethiopia, Kenya, Nigeria and Tanzania, and a few in Asia, such as Bangladesh, India, Nepal and Pakistan) where their national policy recommends treatment of 2-59 months old children with chest-indrawing pneumonia on an outpatient basis.

When is the study starting and how long is it expected to run for?
April 2021 to June 2025

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Yasir Bin Nisar, nisary@who.int (Switzerland)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Understanding current childhood pneumonia management practices in a few selected low- and middle-income countries: A multi-country prospective observational study

Acronym
Chest Indrawing PneumoniA Management (CIPAM) study

Study objectives

What is the management and outcome (regarding survival status) of 2-59-month-old children presenting with chest-indrawing pneumonia at a primary health care facility in a programme setting?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/10/2021, WHO ERC (Avenue Appia 20, Geneva, 1202, Switzerland; +41 22 791 21 11; ercsec@who.int), ref: ERC.003621

Study design
Multi-country prospective observational study

Primary study design
Observational

Secondary study design
Nested case-control study

Study setting(s)
Community, GP practice

Study type(s)
Other, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chest-indrawing pneumonia

Interventions
The scope of this study is to understand the current management and outcomes for children 2-59 months of age with chest-indrawing pneumonia presenting at primary-level healthcare facilities in high-burden pneumonia countries. Our approach is to conduct a multi-country, observational cohort study to understand the treatment of 2-59-month-old children with chest-indrawing pneumonia and study their outcomes after 15 days of their initial presentation at the primary level facility. The health facility staff will manage these children according to the standard protocols (IMCI). The research team will contact the caregivers of these children on day 15 (±2 days) to collect information about the vital status and treatment received during the last two weeks.

Intervention Type
Other

Primary outcome measure
Survival status of 2-59 month-old children with chest-indrawing pneumonia who presented at the primary health care facility in a programme setting measured using the information provided by the caregivers by day 15

Secondary outcome measures
The management (including oral treatment, which one, for how many days, or hospitalisation, with injectable antibiotics, how many days, and treatment adherence) of children 2-59 months of age with chest-indrawing pneumonia presenting at the primary health care facility in a programme setting measured using the information provided by the caregiver, medical records, and the availability of medicines or any prescription at day 15

Overall study start date
30/04/2021

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Age 2-59 months old
2. Living in a geographic area where follow-up for 15 days can be accomplished
3. Presenting to a first-level health facility with chest-indrawing pneumonia

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
2500

Key exclusion criteria
1. Age <2 months or >5 years
2. Any general danger signs (convulsion, inability to drink or breastfeed, vomiting everything, lethargic/unconscious)
3. Stridor in a calm child
4. Oxygen saturation (SpO2) <90%
5. Currently included in any other study

Date of first enrolment
01/11/2022

Date of final enrolment

31/12/2024

Locations

Countries of recruitment
Ethiopia

India

Nigeria

Pakistan

Uganda

Zambia

Study participating centre
University of Gondar
Maraki 196
Gondar
Ethiopia
0000

Study participating centre
The INCLEN Trust International
F-1/5, Okhla Industrial Area Phase - 1
New Delhi
India
110020

Study participating centre
University of Ibadan
Oduduwa Road
Ibadan
Nigeria
200132

Study participating centre
Trust for vaccine and Immunization (TVI)
Suite No 301, Al-Sehat Centre, Adj Regent Plaza Hotel Rafiqui Shaheed Road

Karachi
Pakistan
-

Study participating centre
International Research Force (IRF)
Islamabad Stock Exchange Tower, Block J F 7/1 Blue Area
Islamabad
Pakistan
44000

Study participating centre
Makerere University
7062 University Road
Kampala
Uganda
-

Study participating centre
The University of Zambia
University of Zambia Great East Road Campus
Lusaka
Zambia
-

Sponsor information

Organisation
World Health Organization

Sponsor details
Ajantha Kumari Ranajeewa
Avenue Appia 20
Geneva
Switzerland
1202
+41 22 791 4303
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Sponsor type
Charity

Website
https://www.who.int/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
The study findings will be disseminated locally, nationally and internationally. Peer-reviewed journal publications, and country-level dissemination meetings with MOH and other stakeholders.

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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 article	19/06/2024	21/06/2024	Yes	No
Results article	28/03/2025	31/03/2025	Yes	No
Results article	04/08/2025	04/08/2025	Yes	No