ISRCTN14120515 https://doi.org/10.1186/ISRCTN14120515

Accuracy of ChARM automated respiratory rate counter in detecting fast breathing pneumonia in children

Submission date
16/09/2024

Recruitment status
No longer recruiting

Registration date
19/09/2024

Overall study status
Completed

Last Edited
19/09/2024

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
According to the WHO Integrated Management of Childhood Illness (IMCI) guidelines, the diagnosis of pneumonia is primarily based on fast breathing. Identifying fast breathing is challenging, often leading to misdiagnosis of pneumonia and inappropriate treatment. Some improved pneumonia diagnostics (e.g., ChARM) can automatically count respiratory rate (RR) and identify fast breathing. This study aims to evaluate the performance of ChARM in counting RR in terms of accuracy and time to count RR.

Who can participate?
Children under 5 years of age presenting at the participating health facilities with suspected pneumonia (e.g., cough and/or difficulty breathing)

What does the study involve?
The children's RR will be measured using the ChARM device, and simultaneous chest movements will be video recorded. The video recordings were then sent to an expert panel for video RR interpretation. The accuracy of the ChARM device in counting RR will be assessed by comparing it to the expert panel's interpretation, which serves as the reference standard.

What are the possible benefits and risks of participating?
There were no direct benefits from participating in this study, but the results may help improve the diagnosis of pneumonia in children in the future. No risks were anticipated from participation in this study.

Where is the study run from?
The study is run by the Projahnmo Research Foundation, a non-governmental organization (NGO) based in Bangladesh.

When is the study starting and how long is it expected to run for?
July 2021 to April 2023

Who is funding the study?
The NIHR Global Health Research Unit on Respiratory Health (RESPIRE) at the University of Edinburgh funded the study

Who is the main contact?
Dr Ahad Mahmud Khan, Associate Scientist, Projahnmo Research Foundation, akhan@prfbd.org, ahad_mahmud@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Ahad Mahmud Khan

ORCID ID
http://orcid.org/0000-0002-4347-0825

Contact details
Projahnmo Research Foundation, Floor 7, House: 97A, Road: 25, Block # A, Banani
Dhaka
Bangladesh
1213
+8801710574858
akhan@prfbd.org

Type(s)
Public

Contact name
Dr Ahad Mahmud Khan

Contact details
Projahnmo Research Foundation, Floor 7, House: 97A, Road: 25, Block # A, Banani
Dhaka
Bangladesh
1213
+8801710574858
ahad_mahmud@hotmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Accuracy of ChARM automated respiratory rate counter in detecting fast breathing pneumonia in children

Acronym
CHARM-RR

Study objectives
The ChARM automated respiratory rate counter demonstrates comparable accuracy in detecting fast breathing pneumonia in children when compared to the reference standard of a video expert panel

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/07/2021, Bangladesh Medical Research Council (BMRC) (BMRC Bhaban, Mohakhali, Dhaka, 1212, Bangladesh; +8802-222298396; info@bmrcbd.org), ref: 39315022021

2. Approved 29/11/2021, Edinburgh Medical School Research Ethics Committee (EMREC) (The University of Edinburgh, College of Medicine and Veterinary Medicine, Teviot Place, Edinburgh, EH8 9AG, United Kingdom; +44 (0)131 650 1000; emrec@ed.ac.uk), ref: 21-EMREC-040

Study design
Multicenter observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Diagnosis of fast breathing pneumonia in children

Interventions

Identification of fast-breathing pneumonia using the ChARM automated respiratory counter with a video expert panel as the reference standard.

The children's respiratory rate will be measured using the ChARM device, and simultaneous chest movements will be video recorded. The duration of observation is approximately 30 minutes. This will be done once, with no follow-up. The video recordings will then be sent to an expert panel for interpretation of the respiratory rate.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Children’s Automated Respiration Monitor (ChARM)

Primary outcome measure
The accuracy of ChARM in classifying fast breathing measured by comparing fast breathing detected by ChARM at enrollment with fast breathing assessed by the expert video panel.

Secondary outcome measures
The time taken by ChARM to count the respiratory rate was measured using a stopwatch or ARI timer at enrollment

Overall study start date
18/07/2021

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Infants under two months presenting with any illness
2. Children aged 2-59 months presenting with cough and/or difficulty breathing

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Months

Upper age limit

59 Months

Sex
Both

Target number of participants
350

Total final enrolment
339

Key exclusion criteria
1. Children presenting with any danger sign
2. Parents who refused to provide consent

Date of first enrolment
06/12/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Bangladesh

Study participating centre
Institute of Child and Mother Health
Matuail
Dhaka
Bangladesh
1362

Study participating centre
Zakiganj Upazila Health Complex
Zakiganj
Sylhet
Bangladesh
3190

Study participating centre
Suprakandi Community Clinic
Zakiganj

Sylhet
Bangladesh
3190

Study participating centre
Bhuyar Bazar Community Clinic
Zakiganj
Sylhet
Bangladesh
3190

Study participating centre
Bakarshal Community Clinic
Zakiganj
Sylhet
Bangladesh
3190

Sponsor information

Organisation
University of Edinburgh

Sponsor details
Old College, South Bridge
Edinburgh
Scotland
United Kingdom
EH8 9YL
+44 (0)131 650 1000
d.balharry@ed.ac.uk

Sponsor type
University/education

Website
https://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
NIHR Global Health Research Unit on Respiratory Health (RESPIRE) at The University of Edinburgh

Results and Publications

Publication and dissemination plan
Dissemination will be through conference presentations and publications in peer-reviewed journals.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the DataStore repository at the University of Edinburgh, UK (https://library.ed.ac.uk/research-support/research-data-service).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Thesis results		25/10/2023	17/09/2024	No	No
Participant information sheet	PIS and consent form version 3.0	03/11/2023	19/09/2024	No	Yes
Protocol article		15/11/2022	19/09/2024	Yes	No