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Cooking and pneumonia study

Submission date
28/06/2013

Recruitment status
No longer recruiting

Registration date
03/07/2013

Overall study status
Completed

Last Edited
20/12/2016

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Malawi has one of the highest rates of death among infants and children under five years of age (69 and 110 per 1000 live births respectively in 2009). Pneumonia (lung disease) is the leading cause of death with around 298 per 1000 children under the age of 5 diagnosed with pneumonia every year and a death rate between 2.7 and 13.2 per 1000 children. Exposure to smoke produced when biomass fuels (animal or plant material) are burned in open fires is a major avoidable risk factor for pneumonia. In Malawi, where at least 95% of households depend on biomass as their main source of fuel, biomass smoke exposure is likely to be responsible for this disease. Efficient methods for reducing smoke exposure exist (e.g. ventilation, improved stoves, cleaner fuels, behaviour changes) but are out of reach for the majority due to many reasons that are mostly poverty related. The Global Alliance for Clean Cookstoves was launched in 2010 to tackle this issue. The main aim of the alliance is for 100 million homes to have clean and efficient stoves and fuels by 2020. However, there is very less evidence to know the potential benefits of such an approach. This study will test an efficient and locally acceptable advanced cookstove that reduces smoke emissions and thereby prevent pneumonia in children.

Who can participate?
All households in included villages with children under the age of 4.5 years will be eligible to participate.

What does the study involve?
Villages in these sites will be randomly allocated to one of two groups: intervention and control groups. Households in the intervention group will receive two advanced cookstoves to use (replacing open fires). Households in the control group will continue to cook in the traditional way. We will look for the occurrence of pneumonia, in children under the age of 5, over two years through health centres and through 3 monthly visits to the villages. In addition, we will study the levels of air pollution in households and exposure to air pollution in individuals in a small group of participants to understand how good the advanced cookstoves are. We will do further research to improve our understanding of how to get the most out of this method if this proves efficient in preventing pneumonia.

What are the possible benefits and risks of participating?
The advanced cookstove is likely to be safer than the open fire since it contains the fire in a stable construction with outside surfaces that are cool to touch during use. All participating

villages will benefit from a mobile phone with airtime and guaranteed treatment of pneumonia in young children. Overall we expect participation in the study will reduce risks to participants. Households will be recruited from populations living in often poor conditions in Malawi who live with relatively high day-to-day risks. The open fire that households in the control group will continue to use is one contributor to these risks..

Where is the study run from?
The study will take place in two sites in Malawi (Chikhwawa and Chilumba).

When is the study starting and how long is it expected to run for?
The study will start in December 2013 and is expected to run till June 2016.

Who is funding the study?
The project is funded by the Joint Global Health Trials scheme that is funded by the Department for International Development (DfID) (UK), the Medical Research Council (MRC) (UK) and the Wellcome Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
N/A

Study information

Scientific Title
An advanced cookstove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomised controlled trial

Acronym
CAPS

Study objectives
An advanced cookstove intervention that substantially reduces biomass smoke exposure relative to an open fire will prevent pneumonia in children under 5 years old in Malawi.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Liverpool School of Tropical Medicine Research Ethics Committee, 14/01/2013
2. Malawi College of Medicine Research and Ethics Committee (COMREC), 10/06/2013, ref. P.11 /12/1308

Study design
Village-level cluster randomised controlled open trial with two arms of equal size

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pneumonia

Interventions
The Philips fan assisted stove with user training (replacing open fires). The Philips stove is an advanced cookstove technology that incorporates a fan to improve combustion efficiency and substantially reduce smoke emissions. Intervention households will receive two of these advanced cookstoves to replace their open fire. In the control arm there will be continuation of traditional cooking methods. Control households will be offered two Philips stoves at the end of their period of participation (2 years).

Randomisation will be by village-level cluster using a computer-generated randomisation schedule with stratification by site, accessibility (distance) of health centre and size.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Primary outcome measure as of 01/07/2016:
Pneumonia episode rate is measured using the WHO IMCI pneumonia assessment protocol from baseline to two years follow up.

Original primary outcome measure:
Pneumonia in children under 5 years of age will be diagnosed by physicians, medical officers or

other appropriately trained staff at local healthcare facilities, blinded to intervention allocation. The WHO IMCI pneumonia assessment protocol will be used to make the diagnosis since chest X-rays are not universally available in the study areas. Briefly, pneumonia is diagnosed using the IMCI protocol by the presence of cough or difficult breathing and signs of pneumonia - fast breathing (60, 50 or 40 breaths per minute or more in those <2 months, 2-12 months and 1-5 years respectively), chest in-drawing, stridor or any general danger sign (inability to drink or breastfeed, vomiting, convulsions, being lethargic or unconscious). Severe IMCI pneumonia is identified by the presence of any general danger sign, chest wall in-drawing or stridor in a calm child. Pneumonia episodes will be recorded over the full 2 years of follow up.

Key secondary outcome(s))
Secondary outcome measures as of 01/07/2016:
1. Severe pneumonia rate is measured using the WHO IMCI pneumonia assessment protocol from baseline to two years follow up, oxygen saturation <90% and death from pneumonia
2. Death rate is measured through our serious adverse event reporting system supplemented by verbal autopsy when possible
3. Respiratory symptoms are measured using a questionnaire at 3 monthly follow up visits
4. Burns are measured using a questionnaire at 3 monthly follow up visits. Where burns meet seriousness criteria these are reported through our serious adverse event reporting system
5. Household air pollution is measured using a combination of questionnaire and air pollution monitoring assessments at various time points
6. Personal exposure to pollution is measured using a combination of questionnaire and air pollution monitoring assessments at various time points
7. Cookstove use is measured using a questionnaire at 3 monthly follow up visits with Stove Use Monitors as well in a sub set of households
8. Economic and health service evaluations are conducted using a range of economic and qualitative research methods

Original secondary outcome measure:
Severe pneumonia and death in children under 5 years of age. We will also assess respiratory symptoms and burns, household air pollution and personal exposure, measure cookstove use and conduct economic and health service evaluations.

Completion date
31/10/2016

Eligibility

Key inclusion criteria
Children up to 4.5 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit

0 years

Upper age limit
4.5 years

Sex
All

Key exclusion criteria
Refusal to participate

Date of first enrolment
01/12/2013

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
Malawi

Study participating centre
Malawi Liverpool Wellcome (MLW) Trust
Blantyre
Malawi
-

Study participating centre
Malawi Epidemiology and Intervention Research Unit (MEIRU)
Chilumba
Malawi
-

Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
The project is funded by the Joint Global Health Trials scheme (http://www.mrc.ac.uk/Fundingopportunities/Calls/Jointghtrials/index.htm) that is funded by the Department for International Development (DfID) (UK), the Medical Research Council (MRC) (UK) and the Wellcome Trust (UK) (Ref:100069/Z/12/Z).

Results and Publications

Individual participant data (IPD) sharing plan

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?
Results article	results	14/01/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes