ISRCTN69058168 https://doi.org/10.1186/ISRCTN69058168

Drinking water under a "One Health" lens: quantifying microbial contamination pathways between livestock and drinking water

Submission date 11/12/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2017	**Overall study status** Completed	
Last Edited 23/04/2021	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Diarrhoeal disease and lack of access to safe water remain significant public health issues in developing countries. There is also growing concern about the potential for disease, including diarrhoeal infections, to be transmitted from livestock to humans. This project addresses the potential drinking-water contamination risks to human health in rural sub-Saharan Africa, where people and livestock often live in close proximity. Preliminary fieldwork will be carried out in rural Kenya, building on an ongoing study that is simultaneously recording human and livestock disease in ten villages. The fieldwork will test different techniques to identify contamination hazards from livestock, alongside water quality testing and recording of diarrhoea in children. These techniques will include checklists for recording signs of livestock hazards at water sources and around water stored in the home. The aim of this study is to look at how feasible it is to record hazards using these techniques and statistically assess whether we find greater water contamination and greater diarrhoea in children where there are more recorded hazards.

Who can participate?
Children aged 6-59 months old and their households.

What does the study involve?
Participants who agree to take part in the study are asked about how they store, treat and handle water in the home, as well as livestock-keeping, handwashing and sanitation arrangements. The study team makes observations of potential contamination hazards, both concerning water stored in the home and at water sources. The study team also takes samples of source water and of water stored in the home, testing these for microbial contamination. The team returns 12 weeks later, asking the same questions, taking the same water samples, and making the same observations. Participants are also asked about diarrhea in children 1 week and 13 weeks later as part of the ongoing study of human and livestock disease.

What are the possible benefits and risks of participating?
Where practical to do so, participants are provided with advice on steps that could be taken to reduce contamination risks affecting water sources such as wells or rainwater systems. There is potential for the study team to inadvertently contaminate stored water during sampling.

Where is the study run from?
Kenya Medical Research Institute (Kenya)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr James Wright

Contact information

Type(s)
Public

Contact name
Dr James Wright

ORCID ID
https://orcid.org/0000-0002-8842-2181

Contact details
University of Southampton
Geography and Environment
Highfield
Southampton
United Kingdom
SO17 1BJ

Additional identifiers

Protocol serial number
MR/P024920/1

Study information

Scientific Title
A longitudinal study of child diarrhoea and stored water contamination in rural Kenyan households in relation to livestock management and ownership

Acronym
OneHealthWater

Study objectives
Livestock management and ownership affects faecal contamination of household stored water and thereby diarrhoea in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Kenya Medical Research Institute Scientific and Ethics Review Unit, 17/10/2017, ref: KEMRI /SERU/CGHR/091/3493
2. Ethics Committe of the Faculty of Social, Human and Mathematical Sciences, University of Southampton, 20/07/2017, ref: 25247

Study design
Prospective observational longitudinal study at a single centre, Siaya County, Kenya, with two sets of observations taking place in wet and dry seasons in a six month period

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Self-reported diarrhoeal disease

Interventions
Participants who give their informed consent to participate in the study are asked via questionnaire interview about how they store, treat and handle water in the home, as well as livestock-keeping, handwashing and sanitation arrangements. Recording observations and questionnaire responses via cell phone data entry, the study team makes observations of potential contamination hazards, both concerning water stored in the home and at water sources. The study team also takes samples of source water and of water stored in the home, testing these for two faecal indicator bacteria groups, E. coli and intestinal enterococci. The team then returns 12 weeks after baseline to administer the same questionnaire, taking the same water samples and testing these for faecal indicator bacteria, and making the same observations. Participants are also asked via questionnaire interview about diarrhea in children 1 week and 13 weeks after baseline, via their participation in the ongoing linked human and animal disease syndromic (PBASS) study. The total duration of observation is thus 13 weeks with 12 weeks of follow-up, thereby observing conditions in both wet and dry season.

Intervention Type
Other

Primary outcome(s)
E. coli and intestinal enterococci in household stored water are measured respectively through membrane filtration (0.45µm pore size) and culture with chromogenic coliform agar medium (incubation period: 24 hours) and m-Enterococcus agar medium (incubation period: 48 hours), followed by enumeration of both target organisms at baseline and 12 weeks thereafter.

Key secondary outcome(s))

Self-reported diarrhea (defined as ≥3 loose stools within a 24-hour period) is measured using questionnaire interview to household members at 1 week and 13 weeks.

Completion date
14/12/2018

Eligibility

Key inclusion criteria
1. Children aged 6-59 months (as the cohort at greatest risk of diarrhoeal disease) in households
2. Participating in an ongoing population-based animal syndromic surveillance (PBASS) study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
59 months

Sex
All

Total final enrolment
234

Key exclusion criteria
Child's carer/parent unavailable or unable to provide informed consent

Date of first enrolment
13/02/2018

Date of final enrolment
29/03/2018

Locations

Countries of recruitment
Kenya

Study participating centre

Kenya Medical Research Institute
Kisumu
Kenya
PO Box 1578-40100

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository at http://doi.org/10.5255/UKDA-SN-854302.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2020	23/04/2021	Yes	No
Basic results		07/06/2020	11/06/2020	No	No
Other files	Consent form version v1.5	14/12/2017	09/08/2018	No	No
Participant information sheet	version v1.5	14/12/2017	09/08/2018	No	Yes
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