

Improving diarrhoea management in children through the development of rotavirus diarrhoea diagnostic kits and viral diarrhoea awareness to reduce diarrhoea illness and death

Submission date 18/05/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/06/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/12/2024	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diarrhoea causes illness and death in many children below 5 years old worldwide but about 90% of these sicknesses and death occur in Asia and Africa. In Nigeria, a lot of children die of diarrhoea. A virus called rotavirus is the major microorganism (or pathogen) causing diarrhoea in children but in Nigeria and many African countries, this virus is not usually diagnosed when they bring children to the hospital for diarrhoea. This is because the available tests that can detect the virus (PCR or ELISA) are time-consuming, requires the training of staff and big equipment and are also expensive. This affects the proper management of children having diarrhoea as almost all the children are given antibiotics. One way to reduce the unnecessary use of antibiotics and to help in the proper management of diarrhoea in children in low-income countries is to develop a quick, easy to perform and cheap kit that can detect rotavirus. No one knows if the developed kit will work well like PCR and ELISA when children have diarrhoea. This study aims to develop the kit and compare if it works well like PCR and ELISA by using the three kits to detect rotavirus in the stool of children with diarrhoea and those without diarrhoea to avoid false-positive results. The goal is to make available a quick, bedside, easy to perform and cheap rotavirus kit in poor countries and also to check the factors responsible for contracting diarrhoea and having severe diarrhoea in children using a questionnaire. The findings of this study should help to improve diarrhoea management thereby reducing deaths due to diarrhoea in children and reducing the unnecessary use of antibiotics in children.

Who can participate?

Children aged from 0 to 60 months who have diarrhoea and healthy children in the same age group who will serve as a control group

What does the study involve?

Parents who come to the hospital with their child/children having diarrhoea and those who come for immunization only are asked to agree on behalf of their children that their children could join the study. The children having diarrhoea are the cases while healthy children without diarrhoea

who come for immunization are the controls. Stool samples will be collected from both groups and they will fill out questionnaires. The presence or absence of rotavirus in the stool will be tested in the laboratory.

What are the possible benefits and risks of participating?

The parent, guardian or caregiver will be informed about rotavirus and the importance of personal hygiene for its prevention. The test result will also be provided at no cost to interested parents. Indirect benefits will be the development of bedside quick, easy to perform, cheap and effective kit which can be used to detect rotavirus for proper diarrhoea management. There is no risk whatsoever associated with participating in this study.

Where is the study run from?

The study is run by the Virology and Molecular Biology Research Group of the Obafemi Awolowo University, Ile-Ife and will take place at Obafemi Awolowo University Teaching Hospital (OAUTHC), Ile-Ife and its attached complex elsewhere, exclusively for children, called OAUTHC Comprehensive Health complex, Eleyele, Ile-Ife (Nigeria)

When is the study starting and how long is it expected to run for?

September 2020 to August 2023

Who is funding the study?

European and Developing Countries Clinical Trials Partnership (EDCTP) (Netherlands)

Who is the main contact?

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Study website

<https://vmbrg.oauife.edu.ng>

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

ERC/2021/04/12

Study information

Scientific Title

Diarrhoea management through the development of nanoparticle-based rotavirus diarrhoea diagnostic kits and viral diarrhoea awareness

Acronym

TMA2019CDF-2731

Study objectives

The study aims are to:

1. Develop a cheap, rapid nanotechnology-based rotavirus Group A (RVA) kit to help clinicians in prompt RVA diarrhoea diagnosis, improve diarrhoea management and reduce the indiscriminate use of antibiotics in children
2. Determine the prevalence of diarrhoea in a case-control RVA epidemiological study using commercial ELISA, PCR and the developed kit in order to assess the diagnostic accuracy of the developed kit
3. Determine the specificity and sensitivity of the developed kit in comparison with that of the commercial ELISA and PCR in the RVA epidemiological study
4. Find out the environmental, clinical/risk factors and seasonal patterns associated with diarrhoea incidence in the study population and if these factors can be used to control diarrhoea prevalence by strengthening preventive methods

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/04/2021, Obafemi Awolowo University Teaching Hospital (OAUTHC) Ethics and Research Committee (ERC) (Ile-Ife, Nigeria; +234 (0)8152092751, +234 (0)8152092755, +234 (0)8152092999; oauthcethicalcommittee@yahoo.com), ref: IRB/IEC/0004553

Study design

Observational longitudinal case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

Rotavirus Group A (RVA) diarrhoea

Interventions

This study involves the collection of stool samples from children (0-5 years) presenting with diarrhoea in Ile-Ife in the southwestern part of Nigeria. Controls (children without diarrhoea for the past 14 days) will also be obtained from children in the same age group and attending the same hospital for the purpose of vaccination. A rotavirus diagnostic kit will be developed using nanotechnology involving lactoferrin (LF), magnesium chloride, silicon, and monoclonal antibody to the VP6 gene, a group-specific antigen found in all RV that cause disease in humans. Rotavirus will be detected by serology (ELISA) and molecular methods. Sociodemographic, environmental /clinical/risk factors associated with diarrhoea will also be obtained using a structured questionnaire. To access the diagnostic accuracy of the developed kit, ELISA and PCR RVA positive and negative samples will be tested using the nanoparticle kit and the sensitivity /specificity of these methods will be compared. Thereafter, findings from this research will be used to carry out a community/media campaign against RVA diarrhoea.

Intervention Type

Other

Primary outcome measure

RVA detected using ELISA, PCR and the developed nanoparticle-based RVA kit at the end of 1-year sample collection

Secondary outcome measures

Sociodemographic, environmental/clinical/risk factors associated with diarrhoea assessed using a structured questionnaire during the 1-year study period

Overall study start date

01/09/2020

Completion date

30/08/2023

Eligibility

Key inclusion criteria**Cases:**

1. Children (aged 0 to 60 months)
2. Acute diarrheal episode (diarrhoea will be defined as three or more loose stools in the last 24 hours with or without other symptoms such as fever, vomiting or dehydration and the onset must be within the last 7 days)

Controls:

1. Healthy children coming to the same hospital/health centre for routine immunization and not presenting with gastroenteritis symptoms for the past 14 days

Participant type(s)

Healthy volunteer, Patient

Age group

Child

Lower age limit

0 Months

Upper age limit

60 Months

Sex

Both

Target number of participants

170

Total final enrolment

186

Key exclusion criteria**Cases:**

1. Children who do not have diarrhoea
2. Children older than 5 years
3. Parents or guardians do not give formal consent to participate in the study

Controls:

1. Sick children
2. Children older than 5 years
3. Parents or guardians do not give formal consent to participate in the study

Date of first enrolment

21/06/2021

Date of final enrolment

20/06/2022

Locations

Countries of recruitment

Nigeria

Study participating centre

Obafemi Awolowo University Teaching Hospital

Phase 3

Ile-Ife

Nigeria

-

Sponsor information

Organisation

Obafemi Awolowo University

Sponsor details

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Sponsor type

University/education

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Funder(s)

Funder type

Research organisation

Funder Name

European and Developing Countries Clinical Trials Partnership

Alternative Name(s)

Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaio Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in open access high impact factor journal

Intention to publish date

21/08/2025

Individual participant data (IPD) sharing plan

The dataset will not be made available to the public as part of the confidentiality agreement during the ethics application to ensure confidentiality and protection of individual data. Hence, key linking codes to the subject name will be used and data will be stored in encrypted form in a dedicated computer which is passworded. The PI and data manager have access to the code. Hard copies of collected data and forms are in a secured cabinet with limited access to individuals (Principal investigator and data manager). Raw data will not be available to the public, but results will be reported in aggregates in scientific journals or meetings without reference or links to the subjects. Data will be destroyed after 5 years

The data on the questionnaire is imputed on the dedicated system as samples are collected and results will be imputed on the same PC against each child's code as soon as stool analysis results are available. Questionnaires are identified with the given code numbers matched with the sample bottles for each child, to further avoid misrepresentation, ensure confidentiality and keep all personal information collected during the study confidential. Each sample has the same code with the filled questionnaire and informed consent and subject information forms filled by the parent/guardian for proper documentation. A dedicated computer is used for inputting the data, using the key linking codes. A data manager is responsible for inputting the data on the questionnaire in the private computer which is password protected, with the PI and data manager having access to the code. Also, to avoid data loss, the data is uploaded to Google Drive and updated regularly. Hard copies of collected data and forms are in a secured cabinet with limited access to individuals (principal investigator and data manager). Raw data will not be available to the public but results will be reported in aggregates in scientific journals or meetings without reference or links to the subjects.

IPD sharing plan summary

Not expected to be made available