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3ACP Malawi: Enhancing access to COVID-19 tests. Africa, Asia, Americas COVID-19 Preparedness (3ACP)

Submission date
16/05/2023

Recruitment status
No longer recruiting

Registration date
26/05/2023

Overall study status
Completed

Last Edited
28/06/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The World Health Organization (WHO) has released guidelines supporting the use of rapid antigen tests for diagnosing SARS-CoV-2, including self-testing. These tests are commonly used in wealthy countries. However, the policies and practices regarding the use of antigen rapid diagnostic tests (Ag-RDTs) are not well-defined in most African countries, including Malawi. It is important to incorporate affordable rapid testing into regular healthcare services in order to promptly diagnose individuals at high risk of COVID-19 and make them eligible for oral antiviral treatments. While self-testing strategies using Ag-RDTs are already implemented in many COVID-19 testing approaches funded by governments in wealthy countries, self-test kits that can be purchased over the counter are not yet supported by policies in low- and middle-income countries for COVID-19 self-testing.

In this study, we aim to compare the number of confirmed COVID-19 cases diagnosed within five days of experiencing symptoms between two groups: one group receiving twice-weekly COVID-19 self-test kits and the other group receiving the standard of care. The standard of care includes considering the number of days off work due to suspected or confirmed COVID-19. All positive results from the COVID-19 self-tests will then undergo confirmation through polymerase chain reaction (PCR) testing and/or testing by a provider using Ag-RDTs (standard of care group). The goal is to detect infections early and enable effective infection prevention and care.

Who can participate?
Health care workers (HCWs) in Blantyre District i.e. both urban and rural public primary health centres. There will be six intervention health facilities under and six facilities under the standard of care arm.

What does the study involve?
For this study, we will conduct a controlled study with two groups, but the assignment to each group will not be random. In the standard of care group, we expect an average count of 20 and 35 confirmed cases of COVID-19 diagnosed within three months, with a standard deviation of 12.

In the intervention group, the confirmed cases will be determined either by PCR testing or by repeating the antigen rapid diagnostic test (Ag-RDT) with the help of a professional. There will be a total of six clusters in each group, and each cluster will consist of 100 healthcare workers (HCWs).

What are the possible benefits and risks of participating?
-Potential direct benefits to you for participation in the study include easy access to COVID 19 testing, early detection COVID, and prevention of spread to high risk individuals you closely associate with.
-During participation in this study you may experience discomfort in your nose as the nasal swab is inserted. It is expected that this discomfort will go away soon after sample collection. If correct sampling technique is followed, the risk of complications from the procedure is low. Though rare, expected complications may be nasal bleeding or broken swab if excess pressure was applied. If you experience any of these problems, please report to study staff and you will be referred for appropriate treatment.
-You may also obtain a positive COVID-19 from your self-test, which may worry you. The researcher will discuss the meaning of the results with you and refer you to the national COVID-19 program where you will get help.
-On a more unlikely note, although we will conduct the study activities in private, it is possible that some people may know of your study participation and assume that you have COVID-19. This may affect your social or business relationships.

Where is the study run from?
Unitaid (Switzerland)

When is the study starting and how long is it expected to run for?
August 2022 to May 2023

Who is funding the study?
Unitaid (Switzerland)

Who is the main contact?
Dr Augustine Talumba Choko, achoko@mlw.mw

Contact information

Type(s)
Principal Investigator

Contact name
Dr Augustine Choko

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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
Evaluating the acceptability and feasibility of COVID-19 testing and linkage including self-testing: linked prospective studies in Malawi

Acronym
3ACP Malawi

Study objectives
There will be higher numbers of early COVID-19 diagnosed in the arm offering twice-weekly COVID-19 self-test kits to health care workers compared to the standard of care arm

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 21/06/2022, College of Medicine Research and Ethics Committtee ;), ref: (Private Bag 360, Chichiri, Blantyre 3, -, Malawi; +265 888 118 993; comrec@medcol.mw), ref: P.05/22 /3649

2. Approved 31/05/2022, London School of Hygiene and Tropical Medicine (Keppel Street, London , WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 26874

3. Approved 08/11/2022, World Health Organization COVID Ethics Review Committee (20, Avenue Appia, Geneva 27, CH-1211, Switzerland; +41 22 791 21 11; ct_ethics@who.int), ref: CERC.0163

Study design
Non randomized cluster trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Screening

Participant information sheet

Health condition(s) or problem(s) studied
SARS-COV-2

Interventions
Standard of care (SOC) arm with professional-use rapid diagnostic tests (C19RDTs) for diagnostic testing of symptomatic HCWs.
Intervention arm with SOC plus twice-weekly COVID-19 Ag-RDT self-testing (C19ST) for all health workers (HCWs).

Intervention Type
Device

Pharmaceutical study type(s)
Self-test kit

Phase
Phase III

Drug/device/biological/vaccine name(s)
ACON Flowflex™ COVID-19 Antigen Home Test

Primary outcome measure
Harmonic mean number of HCWs with confirmed COVID-19 measured through a count of number of HCWs with confirmed COVID-19 by PCR or rapid testing.

Secondary outcome measures
Measured by self-report at one month follow-up face-to-face interview:
1. Health care workers reporting any illness in the last 28 days
2. Health care workers taking time off work in the last 28 days
3. Health care workers having cough and fever in the last 28 days

Overall study start date
01/08/2022

Completion date
30/05/2023

Eligibility

Key inclusion criteria
Healthcare workers shall be eligible to participate if they are:
1. Aged 18 years and above
2. All health workers employed by the above facilities, including nurses, doctors, clinic assistants, health surveillance assistants, clinical officers, community health workers and lay counsellors, administrators and support staff such as receptionists and porters.
3. Willing and able to give written informed consent

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
1,200

Total final enrolment
1081

Key exclusion criteria
A healthcare worker shall be ineligible to participate if they:
1. Have tested positive for COVID-19 and are still within the isolation period
2. Have any medical contraindication to anterior nasal swab (e.g. bleeding disorders, recent facial trauma)

Date of first enrolment
28/12/2022

Date of final enrolment
30/05/2023

Locations

Countries of recruitment
Malawi

Study participating centre

Ndirande health centre
Blantyre
Malawi
265

Study participating centre
Zingwangwa health centre
Blantyre
Malawi
265

Study participating centre
Bangwe health centre
Blanytre
Malawi
265

Study participating centre
Chileka health centre
Blantyre
Malawi
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Study participating centre
Dziwe health centre
Blantyre
Malawi
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Study participating centre
Mpemba health centre
Blantyre
Malawi
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Study participating centre

Lirangwe health centre
Blanyre
Malawi
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Study participating centre
Mdeka health centre
Blantyre
Malawi
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Study participating centre
Mdeka health centre
Blantyre
Malawi
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Study participating centre
Chichiri health centre
Blantyre
Malawi
265

Sponsor information

Organisation
Unitaid

Sponsor details
Unitaid – Global Health Campus
Chemin du Pommier 40, 5th floor
1218 Grand-Saconnex
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Sponsor type
Charity

Website
https://unitaid.org/

ROR
https://ror.org/05t99je22

Funder(s)

Funder type
Research organisation

Funder Name
Unitaid

Results and Publications

Publication and dissemination plan
The results will be used to inform MoH on COVID-19 scale-up plans and will also be disseminated through Kamuzu University of Health Sciences, and through conference presentations and publication in peer-reviewed journals. The results will also be shared with participants and stake holders through the District Executive Committees (DEC), Health and Environment Committees (HEC), and the District Health Management Teams (DHMT) of Blantyre

Intention to publish date
30/10/2024

Individual participant data (IPD) sharing plan
Data will be shared after anonymization and de-identification via https://datacompass.lshtm.ac.uk/

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	01/06/2022	17/05/2023	No	Yes
Protocol file	version 4.0	11/11/2022	17/05/2023	No	No