



PARTICIPANT INFORMATION SHEET

Participant information sheet

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



What is the benefit and unintended consequences of using antibiotic treatment as a way of excluding tuberculosis disease in patients with cough?

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One of our team will go through this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?

Tuberculosis (TB) is a disease that causes a long illness and cough with sputum. Although curable TB is difficult to detect. When they fail to detect TB after testing sputum, clinicians give antibiotic treatment that can cure all other causes of TB symptoms but not TB. In this approach, TB is considered ruled out if patient gets better and it is considered likely if they do not get better. The goal of this research study is to develop understanding of how well the antibiotics help distinguish TB patients from those who do not have it, whether giving antibiotics carries other health benefits, and whether it leads to development of disease causing organisms which are resistant to drugs.

We will learn about this by comparing a group of patients given antibiotics on the first day of the study to another group not given antibiotics. There will be two groups receiving antibiotics as follows: 1) Azithromycin taken as one tablet once a day for 3 days, and 2) Amoxicillin 4 capsules taken three times a day for 5 days. The group you will go into, out of the three, will be decided by chance so you can fall into any group.

What will be involved if I accept to participate in the study?

We are considering you for participation in this study because you told us that you have a cough. Any patient who has been coughing for at least 2 weeks, is at least 18 years, and lives within Blantyre, is eligible to participate in this study if they do not have signs consistent with serious illness. Apart from you, we will recruit 1,874 other individuals.

Study activities will be performed the first day, at 1 week (Day 8), and at one month (Day 29). At each of these study visits, we will ask you questions about your contact details, your health, use of medications, and any illnesses or hospitalisations you may have had in between study visits. We will also document relevant details from your health passport and other clinical documentation you may have.

On Day 1 and at 1 week, we will ask you to submit sputum and urine samples for TB tests. If you are not able to give sputum on Day 1, we will give you containers so that you can bring them the following morning. Some of the sputum TB tests results will become available after 7 days and we will pass them to health center clinicians who will make a plan for your care, the other results may take up to 4 weeks so you will get them at the 1 month visit. Urine TB test results will not be available for your clinical care.

21-May-2019

A copy of this informed consent document to be offered to the participant

Study title: Randomised controlled clinical trial of diagnostic value, clinical benefits and unintended consequences of using trial-of-antibiotics to evaluate ambulatory adults with prolonged cough for tuberculosis in Malawi

Version & Date: 3.0/28 Feb 2019

Principal Investigator: Dr Titus H Divala

Participant Information Sheet

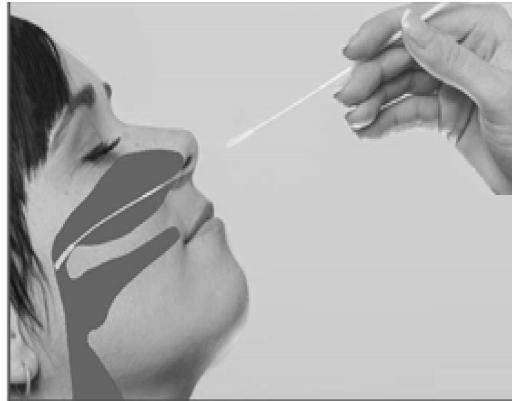
REC ref: LSHTM 15232; COMREC P.04/18/2381

Page 1 of 4



We will also do an HIV test. If the results are confirmed to be HIV positive we will do a viral load test, and at the end of the study activities on Day 1, we will link you to HIV management team here at the health center who will start you on treatment. Should we make a diagnosis of TB or HIV at any other point during the study, we will link you with the responsible health center team for treatment services.

On day 1 and at 1-month visit, we will swab the back of the inside of your nose as shown in this picture to collect germs that live there. We will test the germs for drug resistance. Results of this test are not relevant to your care.



On 1-week visit, we will ask you to report how your health has changed in comparison to how you were on day 1. These questions will be read to you by a computer and you will answer them by choosing various options which it will display during the interview.

The 1 month visit will be the final study visit where we will also provide you with results for TB culture and ask if you have TB symptoms. If you are in HIV or TB care, we will ask how your follow up is going. The appointment with you at 1 months is very important because it will help you to know the results of the TB tests and it will also help us know the status of your health.

The number of clinic visits you will make for this study is at least three. Here we count Day 1, one visit after one week, and another visit at one month. If you have not been able to come here for any of the visits, we will remind you by phone call or we will use the permission and information you will give us to visit you at your home. The first visit will take about 60 minutes and the later visits will take about 30 minutes each.

Will there be any risks involved in this study?

This study is a low risk study. There are no risks involved in submitting sputum or urine for the study. You may feel some discomfort during swabbing of the back of the nose and during blood collection for HIV and viral load tests. Azithromycin and amoxicillin are already widely used in Malawi and rarely cause problems. Rare side effects for azithromycin include feeling nervousness, skin reactions and disturbance of heart function. Rare side-effects for amoxicillin are mental state changes, feeling light-headed, and reactions to sunlight.

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

Will there be any benefits in this study?

The key benefit of this study is that you will have access to a more detailed TB evaluation process than usual. This will help you know if you have TB and to have the opportunity to start TB treatment. The study is also beneficial to health care providers because it will address important questions about use of antibiotics during the TB diagnostic process.

21-May-2019

Will the findings in the study be confidential?

A copy of this informed consent document to be offered to the participant

Study title: Randomised controlled clinical trial of diagnostic value, clinical benefits and unintended consequences of using trial-of-antibiotics to evaluate ambulatory adults with prolonged cough for tuberculosis in Malawi

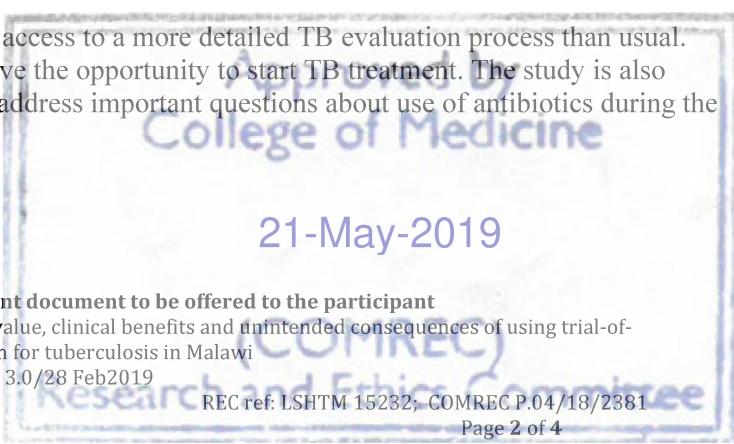
Version & Date: 3.0/28 Feb 2019

Principal Investigator: Dr Titus H Divala

Participant Information Sheet

REC ref: LSHTM 15282; COMREC P.04/18/2381

Page 2 of 4





Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you. Information about TB test result and HIV test results will be recorded using an identification number. However, any records or data obtained as a result of your participation in this study may be used by LSHTM who are sponsoring this study, regulators of health research (COMREC), or by members of the research team. These records will be kept in a locked space in the University of Malawi College of Medicine. Information and samples collected in this study will be retained for up to 10 years after the end of the trial, according to our institution recommendations. These collected samples and other information may also be used for future studies if you give us that consent.

Can I withdraw from the study anytime and will this affect my treatment?

You are free to choose whether or not to participate in this study. While we would like you to participate in the study to the very end, withdrawing at any point is an option that is freely available to you without any penalty or loss of any entitled benefits. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation.

What are the financial benefits of participating in this study?

There will be no payment given to you for participating in the study. The study will provide at least MK8,000 as compensation for your costs of attending the study visits. We will give this money in instalments on scheduled study visits.

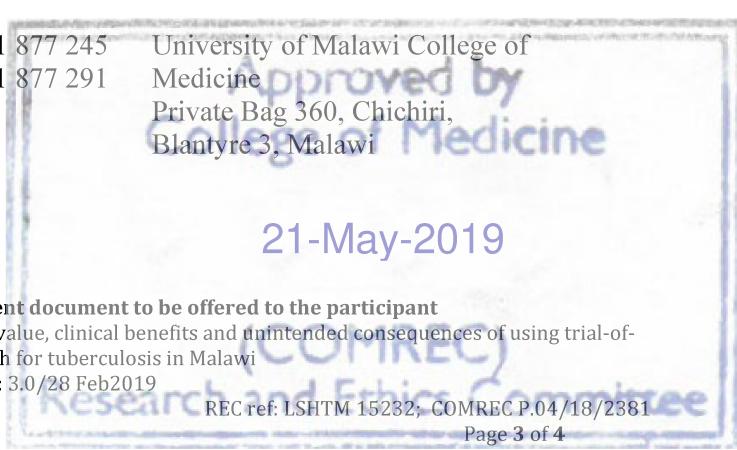
Is this study approved by an ethics committee?

The study has been approved by the London School of Hygiene & Tropical Medicine Research Ethics Committee, and the College of Medicine Research Ethics Committee (COMREC).

Who do you ask if you have questions regarding the study?

If you have any questions concerning participation in this study, please feel free to ask me. Alternatively, you can contact the following people by phone or post:

	Name	Telephone	Postal address
Study investigators	Dr Titus Divala Dr Marriott Nliwasa	0999478376 0888681948	Helse Nord Tuberculosis Initiative University of Malawi College of Medicine Private Bag 360, Chichiri, Blantyre 3, Malawi
COMREC	Administrative officer, COMREC Secretariat	01 877 245 01 877 291	University of Malawi College of Medicine Private Bag 360, Chichiri, Blantyre 3, Malawi



A copy of this informed consent document to be offered to the participant

Study title: Randomised controlled clinical trial of diagnostic value, clinical benefits and unintended consequences of using trial-of-antibiotics to evaluate ambulatory adults with prolonged cough for tuberculosis in Malawi

Version & Date: 3.0/28 Feb 2019

Principal Investigator: Dr Titus H Divala
Participant Information Sheet

REC ref: LSHTM 15282; COMREC P.04/18/2381

Page 3 of 4



What is the benefit and unintended consequences of using antibiotics treatments as a way of excluding tuberculosis disease in patients with cough?

Patient declaration

Statement	Initial or thumbprint each box
I confirm that I have read the above information sheet for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
OR I have had the information explained to by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by authorised individuals from LSHTM, University of Malawi College of Medicine, and COMREC, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that data about me may be shared via a public data repository or by sharing directly with other researchers, and that I will not be identifiable from this information	
I understand that the tissue sample collected from me will be used to support other research in the future, and may be shared anonymously with other researchers, for their ethically-approved projects	
I agree to take part in the above named study	

Printed name of participant	Signature/thumb print of participant	Date

Printed name of impartial witness*	Signature of impartial witness*	Date

I attest that I have explained the study information accurately to _____, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the above named impartial witness (where applicable).

Printed name of staff obtaining consent	Signature of staff obtaining consent	Date

*Impartial witness should be someone the participant trusts. The impartial witness can write the participant name but cannot sign for them. Instead, illiterate participants should use thumbprint in place of signature and the impartial witness should go ahead and sign in designated space.

21-May-2019

A copy of this informed consent document to be offered to the participant

Study title: Randomised controlled clinical trial of diagnostic value, clinical benefits and unintended consequences of using trial-of-antibiotics to evaluate ambulatory adults with prolonged cough for tuberculosis in Malawi

Version & Date: 3.0/28 Feb 2019

Principal Investigator: Dr Titus H Divala

Participant Information Sheet

REC ref: LSHTM 15282; COMREC P.04/18/2381

Page 4 of 4



PARTICIPANT INFORMATION SHEET

Chikalata chofotokozerwa ofuna kutenga nawo mbali

LONDON
SCHOOL OF
HYGIENE
& TROPICAL
MEDICINE



Kodi kugwiritsa ntchito mankhwala opha tizirombo toyambitsa matenda ena ngati njira yothandizira kufifuza chifuwa chachikulu kuli ndi phindu kapena kuipa kotani?

Chiyambi

Tikukupemphani kuti mutenge nawo mbali mu kafukufuku. Ndi chifuniro chanu kulowa mu kafukufukuyu. Musanapange chiganizo, mukuyenera kumvetsa chifukwa chimene kafukufukuyu akuchitikira komanso zimene zitadzachitike. M'modzi mwa anthu a gulu logwira ntchito mu kafukufuku awerenga chikalatachi pamodzi ndi inu, ndipo ayankha mafunso ena aliwonse amene mungakhale nawo. Funsani mafunso ngati simukumvetsa zomwe mwawerenga kapena ngati mukufuna uthenga owonjezera. Muli omasuka kulankhula ndi ena zokhudza kafukufukuyu ngati mukufuna. Ganizani mofatsa musanavomereze kutenga nawo mbali kapena ayi.

Kodi cholinga cha kafukufukuyu ndi chiyani?

Chifuwa chachikulu (TB) ndi matenda amene munthu amkhala chidwalire kwa nthawi yaitali. Odwalayo, amapanga makhololo. Ngakhale chili chochizika, chifuwa chachikulu ndi chovuta kuchipeza. Pamene njira zoyeza makholoro zalephera kupeza chifuwa chachikulu, achipatala amaperekwa mankhwala opha tizirombo toyambitsa matenda amene angathane ndi zonse zimene zimayambitsa zizindikiro za matenda ofanana ndi chifuwa chachikulu. Ngati odwala apeza bwino ndi njira imeneyi amaganiziridwa kuti alibe matenda a chifuwa chachikulu koma ngati sanapeze bwino amaganiziridwa kuti ali ndi chifuwa chachikulu. Cholina cha kafukufuku ameneyu ndi kufuna kumvetsa za m'mene mankhwala amenewa amathandizira kusianitsa odwala matenda a chifuwa chachikulu ndi amene alibe matendawa, ngati mankhwalawa ali ndi phindu lina kwa odwala, komanso ngati kupereka mankhwalawa kukubweretsa tizirombo tosamva makhwala.

Tiphunzira zimenezi pakusianitsa gulu la anthu odwala amene apatsidwa mankhwala opha tizirombo toyambitsa matenda patsiku loyamba la kafukufukuyu ndi gulu lina limene silinapsidwe mankhwalawa. Pakhala magulu awiri olendiria mankhwala opha tizirombo motere: 1) Azithromycin omwedwa pilisi imodzi kamodzi patsiku kwa masiku atatu, komanso 2) Amoxicillin makapusolo anayi omwedwa katatu patsiku kwa masiku asanu. Gulu limene mulowe, mwa magulu atatuwa, lisankhidwa mwa mayere choncho mukhoza kupeze ka mu gulu lina lirilonse.

Kodi chidzachitike ndi chiyani ngati ndingavomereze kutenga nawo mbali mu kafukufukuyu?

Tikukupemphani kuti mutenge nawo mbali mu kafukufukuyu chifukwa mwatiuza kuti muli ndi chifuwa. Odwala wina aliyense amene wakhala akukhosomola kwa masabata osachepera awiri, ali ndi zaka zosachepera 18, ndipo amakhala mu Blantyre muno, atha kutenga nawo mbali mu kafukufukuyu ngati alibe zizindikiro zosonyeza kudwalika kwambiri. Kupatula inu, tilemba anthu ena okwanira 1,874.

Zochitika za kafukufukuyu zidzapangidwa patsiku loyamba, pa sabata imodzi (Tsiku 8), ndi pamwezi umodzi (Tsiku 29). Pa masiku a kafukufuku onsewa, tidzakufunsani mafunso okhuzana ndi m'mene tingalumikizirane nanu, thanzi lanu, kagwiritsidwe ntchito ka mankhwala, ndi matenda ena aliwonse kapena kugonekedwa mu chipatala komwe kungakuchitikireni. Tidzalemba zimbu zofunikira

Mpatseni otenga nawo mbali chikalata chimodzi kuti chikhale chake

Dzina la kafukufuku: Kodi kugwiritsa ntchito mankhwala opha tizirombo toyambitsa matenda ena ngati njira yothandizira kufifuza chifuwa chachikulu kuli ndi phindu kapena kuipa kotani?

Mkulu wakafukufuku: Dr Titus H Divala
Chikalata chofotokozerwa ofuna kutenga nawo mbali

Version & Date: 3/02/28 Feb 2019

REC ref: LSHTM 15232; COMREC P.04/18/2381

Page 1 of 5



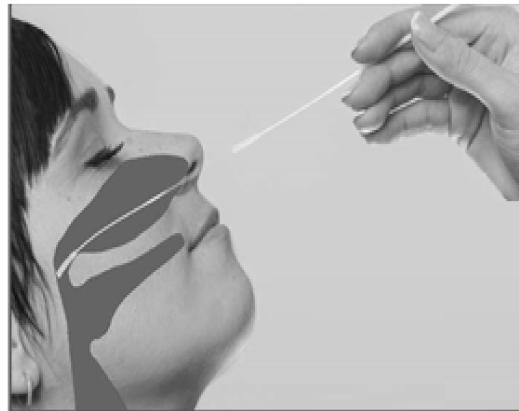
kuchokera mu bukhu lanu la kuchipatala komanso zolembedwa zina za chipatala zimene mungakhale nazo.

Patsiku loyamba ndi pakutha pasabata yoyamba, tidzakufunsani kuti mupereke makhhololo komanso mkodzo pofuna kuyeza matenda a chifuwa chachikulu. Ngati simungakwanitse kupereka makhhololo patsiku loyamba, tidzakupatsani mabotolo kuti mudzawabweretse m'mawa wa tsiku lotsatira. Zotsatira zina za makhhololo zidzatuluka pakutha pa masiku asanu ndi awiri ndipo tidzazipereka kwa matodolo a chipatala chino kuti akuthandizeni, zotsatira zina zidzatenga pafupi-fupi masabata anayi choncho mudzazilandira pa ulendo wa pamwezi umodzi. Zotsatira zanu zoyesa mikodzo ku matenda a chifuwa chachikulu sizidzakhalapo ku nkhanzi ya chisamaliro chanu cha kuchipatala.

Tidzayezango kachirombo ka HIV. Ngati zotsatirazi zasonyeza kuti muli ndi kachirombo ka HIV tidzayenza kuchuluka kwa tizirombo ta HIV, komanso kukutumizani kolandilira chithandizo chamatendawa. Ngati tingakupezeni kuti muli ndi matenda a chifuwa chachikulu kapena kachirombo ka HIV panthawi ina iliyonse mkatı mwa kafukufukuyu, tidzakutumizani kolandilira zithandizo zamatendawa pompano pachipatala.

Patsiku loyamba komanso pa ulendo wa mwezi woyamba, tidzapukuta kumbuyo kwa mkatı mwa mphuno mwanu ngati m'mene zikuonekera pachithunzichi kuti titenge tizirombo timene timakhala m'menemo. Tidzayenza tizirombo timenetı kuti tione ngati tikumva mankhwala. Zotsatira zimenezi sizidzagwirtsidwa ntchito kuchisamaliro chanu chaku chipatala.

Pa ulendo wa sabata yoyamba, tidzakupemphani kuti mutiuze m'mene thanzi lanu lasinthira kuyerekeza ndi m'mene munaliri patsiku loyamba. Mafunso amenewa adzawerengedwa kwa inu kudzera pa makina a kompyuta ndipo mudzawayankha pakusankha mayankho angapo amene makinawa adzawonetse panthawi yomwe azidzafunsa.



Ulendo wa pa mwezi umodzi udzakhala wotsiriza umene tidzakupatseniso zotsatira za zoyesa za matenda a chifuwa chachikulu komanso tidzakufunsani ngati muli ndi zizindikiro za matenda a chifuwa chachikulu. Ngati panthawiyi mudzakhale kuti mukulandira Thandizo la HIV kapena TB, tidzakufuna kudziwa kuti zikuyenda bwanji. Kukumana ndi inu patatha mwezi umodzi ndikofunikira kwambiri chifukwa zidzakuthandizirani kuti mudziwe zotsatira za zoyesa za matenda a chifuwa chachikulu ndipo zidzathandizirano kudziwa zam'mene thanzi lanu liliri.

Maulendo a kuchipatala amene mudzayende a kafukufukuyu ndiwosachepera atatu. Pamenepta tikuwerenga tsiku loyamba, ulendo umodzi pakutha pa sabata imodzi, ndi ulendo umodzi pa mwezi umodzi. Ngati simunakwanitse kubwera kuno pa ulendo wina uliwonse tidzakukumbutsani pokuyimbirani lamya kapena tidzagwirtsia ntchito chilorezo ndi uthengwa umene mudzatipatse kuti tikuyendereni kunyumba kwanu. Patsiku loyamba tidzakhala nanu kwa mphindi makumi asanu ndi imodzi, pamene paasiku ena onse, tidzakhala nanu kwa mphindi makumi atatu.

Kodi padzakhala ziopsezozina zilizonse zochitika mu kafukufukuyu? 21 May-2019

Mpatseni otenga nawo mbali chikalata chimodzi kuti chikhale chake

Dzina la kafukufuku: Kodi kugwirtsia ntchito mankhwala opha tizirombo toyambitsa matenda ena ngati njira yothandizira kufufuza chifuwa chachikulu kuli ndi phindu kapena kuipa kotani?

Mkulu wakafukufuku: Dr Titus H Divala
Chikalata chofotokozerwa ofuna kutenga nawo mbali

Version & Date: 3.0/28 Feb 2019

REC ref: LSHTM 15232; COMREC P.04/18/2381

Page 2 of 5



Kupanga nawo kafukufukuyu sikuika moyo wanu pa chiopsyero chochuluka. Palibe chiopsezo pa kupereka makhololo kapena mikozo mu kafukufukuyu. Mukhoza kusamva bwino panthawi yopukuta kumbuyo kwa mphuno komanso panthawi yotenga magazi oyeza za kachirombo ka HIV ndi kuchuluka kwa tizirombo toyambitsa matendawa. Azithromycin ndi amoxicillin ndi mankhwala oti akhala akugwiritsidwa ntchito kwa nthawi yayitali m' Malawi ndipo sikweni-kweni kuyambitsa mavuto. Patali-patali azithromycin amapangitsa kumva nthumazi, ziwengo, komanso kusokonekera kwa kagwiridwe ntchito ka mtima. Patali-patali amoxicillin amapangitsa kusakhazikika mmanganizo, kumva chizungulire, komanso kutuluka ziwengo munthu akakhala padzuwa.

A London School of Hygiene ndi Tropical Medicine ali ndi thumba landalama zachipukuta misozi lokhudzana ndi kafukufukuyu. Ngati mwawpeteka kapena kuvulala chifukwa chotenga nawo mbali mu kafukufukuyu, mudzakhale omasuka kupempha chipukuta misonzi.

Kodi padzakhala zopindula zina zilizonse mu kafukufukuyu?

Chopindulitsa chodziwika cha kafukufukuyu ndi chakuti mudzakhala ndi mwayi oyezedwa matenda a chifuwa chachikulu mozama kuposa m'mene zimakhalira nthawi zonse. Zimenezi zidzakuthandizirani kudziwa ngati muli ndi matenda a chifuwa chachikulu komanso kukhala ndi mwayi oyamba kulandira thandizo la mankhwala a chifuwa chachikulu. Kafukufukuyu ndi opindindulitsano kwa opereka chisamaliro cha kuchipatala chifukwa adzayankha mafunso ofunikira okhudzana ndi kagwiritsidwe ntchito ka mankhwala opha tizirombo toyambitsa matenda panthawi ya ndondomeko yoyeza matenda a chifuwa chachikulu.

Kodi zotsatira za mukafukufukuyu zidzakhala za chinsinsi?

Chizindikiritso chanu mu kafukufukuyu chidzatengedwa kukhala cha chinsinsi. Zotsatira za kafukufukuyu, zikhoza kudzasindikizidwa ndi cholinga cha sayansi koma dzina lanu kapena chizindikiritso chilichonse chokhudzana ndi inu chidzabisidwa. Uthenga okhudza zotsatira zoyesa matenda achifuwa chachikulu kapena HIV zidzalembewa pogwiritsa ntchito nambala yanu yakafukufuku. Komabe, zina zomwe mungatifikozere zitha kudzagwiritsidwa ntchito ndi amene ali oyang'anira za kafukufuku wa zaumoyo (COMREC) komanso LSHTM. kapena ndi mamembala a gulu la kafukufukuyu. Zolembewazi zidasungidwa mumalo otsekeda bwino ku sukulu ya ukachenjede ya Malawi College of Medicine. Uthenga ndi zoyesa zotengedwa mu kafukufukuyu zidzassungidwa kwa zaka pafupi-fupi khumi (10) pakutha pakuyesaku, malingana ndi ndondomeko ya bungwe lathu. Zoyesa zotengedwazi ndi mauthenga ena zikhoza kugwiritsidwano ntchito pa kafukufuku wamtsogolo ngati mutatipatsa chilolezo chimenecho.

Kodi ndikhoza kusiya kafukufukuyu nthawi ina iliyonse ndipo zimenezi zingadzakhudze thandizo langa la mankhwala?

Muli ndi ufulu kusankha kutenga nawo mbali kapena kusatenga nawo mbali mu kafukufukuyu. Ngakhale tingakonde kuti mutenge nawo mbali mu kafukufukuyu mpaka ku mapeto, kutuluka nthawi iliyonse mukafukufuku ndi chisankho chanu popanda chilango chilli chonse kapena kuluza kulandira thandizo lililonse lomwe mukuyenera kulandira. Munthawi yakafukufukuyu, tidzakudziwitsani patati

21-May-2019

Mpatseni otenga nawo mbali chikalata chimodzi kuti chikhale chake

Dzina la kafukufuku: Kodi kugwiritsa ntchito mankhwala opha tizirombo toyambitsa matenda ena ngati njira yothandizira kufufuza chifuwa chachikulu kuli ndi phindu kapena kuipa kotani?

Mkulu wakafukufuku: Dr Titus H Divala
Chikalata chofotokozerwa ofuna kutenga nawo mbali

Version & Date: 3.0/28 Feb 2019

REC ref: LSHTM 15232; COMREC P.04/18/2381

Page 3 of 5



patuluka mauthenga ena a sayansi ofotokoza zinthu zimene zingakupangitseni kuti mulinalirenso zachisamkho chanu chotenga nawo mbali.

Kodi pali phindu la ndalama lotani pakutenga nawo mbali mu kafukufukuyu?

Sipadzakhala kupatsidwa malipro chifukwa chotenga nawo mbali mukafukufukuyu. Ndalamaya yomwe tidzakupatseni ndi yokwana MK8,000. Ndalamayi tizikupatsani pangonopango pamasiku anu akafukufuku..

Kodi kafukufukuyu ndiwovomerezeka ndi komiti yowona za ufulu wa anthu mukafukufuku?

Kafukufukuyu wavomerezewa ndi London School of Hygiene & Tropical Medicine Research Ethics Committee, ndi College of Medicine Research Ethics Committee (COMREC).

Kodi mungafunse ndani ngati muli ndi mafunso okhudzana ndi kafukufukuyu?

Ngati muli ndi mafunso ena aliwonse okhudza kutenga nawo mbali mukafukufukuyu, chonde khalani omasuka kundifunsa. Munjira ina, mukhoza kulumikizana ndi anthu otsatirawa pa lamya kapena polemba kalata kumakeyala awa:

	Name Dzina	Telephone Lamyia	Postal address Adilesi
Study investigators			
Akulu-akulu akafukufuku	Dr Titus Divala Dr Marriott Nliwasa	0999478376 0888681948	Helse Nord Tuberculosis Initiative University of Malawi College of Medicine Private Bag 360, Chichiri, Blantyre 3, Malawi
COMREC			
	Administrative officer, COMREC Secretariat	01 877 245 01 877 291	University of Malawi College of Medicine Private Bag 360, Chichiri, Blantyre 3, Malawi





Kodi pali phindu lotani komanso zotsatira zosayembekezereka zotani pogwiritsa ntchito mankhwala opha tizirombo toyambitsa matenda ngati njira yothana ndi matenda a chifuwa chachikulu mu anthu amene ali ndi chifuwa?

Chitsimikizo cha odwala

Lembani mubokosi liri kumanjali mawu oyamba adzina lanu kapena dindani ndi chala ngati mukuvomereza

Mfundu yachitsimikizo

Ndikutsimikiza kuti ndawerenga chikalata cha uthenga wa kafukufuku amene watchulidwa m'mwambamu. Ndakhala ndi mwayi woganizira za uthengawu, kufunsa mafunso komanso ndayankhidwa mokhutira.

KAPENA

Ndafotokozeredwa uthengawu ndi akafukufuku mu chilankhulo chimene ndikuchimvetsa. Ndakhala ndi mwayi woganizira za uthengawu, kufunsa mafunso komanso ndayankhidwa mokhutira.

Ndikumvetsa kuti kutenga nawo mbali kwanga ndikosakakamizidwa ndipo ndili ndi ufulu kusiya panthawi ina iliyonse popanda kupereka chifukwa china chilichonse, popanda kukhudza chisamaliro cha kuchipatala kapena ufulu wanga.

Ndikumvetsa kuti magawo ofunikira a zolembedwa zanga za ku chipatala komanso mu kafukufukuyu kuwoneda ndi anthu ovomerezeka aku LSHTM, University of Malawi College of Medicine komanso COMREC, pamene kuli kofunika kutenga nawo mbali mukafukufukuyu.

Ndikupereka chilolezo kwa anthu amenewa kuti athe kuwona za zolembedwa zanga.

Ndikumvetsa kuti zomwe atolere akafukufuku zokhudza ine zikhoza kugawilidwa kwa anthu ena opanga kakafukufuku, ndipo kuti sipadzakhala chizindikiro chilichonse chosonyeza kuti zinachokera kwa ine.

Ndikumvetsa kuti zoyeza za mthupi mwanga zimene zidzatengedwe kwa ine zidzagwiritsidwa ntchito kuthandizira kafukufuku wina mtsogolo, ndipo zikhoza kudzagawidwa mwachinsinsi ndi akafukufuku ena, pa ntchito yavo yovomerezeka ndi malamulo aowona zakafukufuku.

Ndikuvomereza kutenga nawo mbali mu kafukufuku amene watchulidwa pamwambaya.

Dzina la wotenga nawo mbali	Sayini/chidindo cha chala cha wotenga mbali	Tsiku

Dzina la mboni yopanda mbali*	Sayini ya mboni yopanda mbali	Tsiku

Ndikutsimikiza kuti ndafotokoza za uthenga wa kafukufukuyu molondola kwa _____, ndipo zinamveka monga mwakudziwa kwanga ndi, wotenga nawo mbali komanso kuti apereka chilolezo chawo kuti atenge nawo mbali* pamaso pa mboni yopanda mbali imene yatchulidwa pamwambapa (ngati kuli koyenera).

Dzina la wotenga chilolezo	Sayini ya wotenga chilolezo	Tsiku

*Mboni yopanda mbali ikuyenekera kukhala yokhulupiridwa ndi munthu ofuna kutenga nawo mukafukufukuyu. Mboni ikhoza kulemba dzina la munthu ofuna kutenga nawo mukafukufukuyu koma siingasayne mmalo mwake. Munthu ofuna kutenga nawo mukafukufuku, ngati samatha kuwerenga ndi kulemba, asayine ndi chidindo cha chala chake ndipo mboni isayine dzina ndi sayini, pamalo ambone.

Mpatseni otenga nawo mbali chikalata chimodzi kuti chikhale chake

Dzina la kafukufuku: Kodi kugwiritsa ntchito mankhwala opha tizirombo toyambitsa matenda ena ngati njira yothandizira kufufuza chifuwa chachikulu kuli ndi phindu kapena kuipa kotani?

Mkulu wakafukufuku: Dr Titus H Divala
Chikalata chofotokozerwa ofuna kutenga nawo mbali

Version & Date: 3.0/28 Feb 2019

REC ref: LSHTM 15232; COMREC P.04/18/2381

Page 5 of 5