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Contributions to the eradication of malaria carriage in malaria areas in Cameroon with Artemisia tea infusions

Submission date 01/04/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/04/2022	**Overall study status** Completed	
Last Edited 12/04/2023	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Malaria is one of the most common and dangerous diseases in this region (African region) and everyone is exposed to the risk of malaria transmission. The medications and methods that are currently used to help people with malaria are not as good as we would like them to be. In fact, there are some people who when given the malaria medication ACT (artemisinin combined therapies) are not completely cured. There are other people who have malaria but do not have signs of malaria-like fever; they are called carriers because if a female mosquito bites them and aspirates their blood, the mosquito will help in spreading the infection to other people. There is a new medication that may work better in treating all these people. In fact, some people in our region are already drinking this medication to treat malaria. The reason we are doing this research is to find out how the new medication Artemisia afra works in treating malaria in people who have malaria in their blood but do not have a fever, and what quantity these people should take to be completely cured.

Who can participate?
We are inviting all adult students and workers at the University of Buea who are at least 18 years old to participate in the research on the new malaria medication.
This research will involve testing people who are not sick to find out if they have malaria.

What does the study involve?
A malaria rapid diagnostic test (mRDT) will be done and the RDT shows malaria parasite in the blood, another test called qPCR, will be done for confirmation. Those that the qPCR test show malaria in their blood will be prescribed the new medication, Artemisia afra tea infusions, to drink for a maximum period of 4 weeks. During the time that they are taking the treatment, their blood will be tested every week to see how the medication is treating malaria. So, they will be expected to come for follow-up visits to the study site (clinic) every week for 4 weeks after the first visit. We will take blood from your arm using a syringe and needle. Each time we will take about 1ml of this much blood (1/5 of a teaspoon)). In total, we will take about 5mls of this much blood in 5 weeks (a teaspoon full). At the end of the research, in 1 year, any leftover blood samples will be destroyed.

Because we do not know the best effective quantity, mixture, and taste of the new malaria medication, we need to compare different quantities, mixtures, and tastes. To do this, we will put people taking part in this research into 8 groups. The groups are selected by chance, as if by tossing a coin.
Participants in 6 groups will be given the test medication while participants in 2 groups will be given a dummy or pretend tea that does not contain the test substance called a placebo. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.

What are the possible benefits and risks of participating?
By participating in this you will not be at greater risk than you would otherwise be, we do not expect participants to develop any symptoms after receiving the teas because many people in the community have taken it before without developing any symptoms. However, if something unexpected happens, we will provide you with the possible intervention to resolve the event.
If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. There may not be any benefit for you, but your participation is likely to help us to know if the medication decreases malaria parasites in the blood of carriers. We will reimburse the transportation cost during visit days and health insurance will be contracted for participants for 6 months. You will not be given any other money or gifts to take part in this research.

Where is the study run from?
This study is conducted under the control of the University of Buea (Cameroon), the University of Liege in Belgium, the free university of Brussels, and the Louvain catholic university of Belgium.

When is the study starting and how long is it expected to run for?
September 2021 to November 2025

Who is funding the study?
This study is funded by the Belgian government through the Academy of Research and Higher Education Development Cooperation (ARES-CDD)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Emptying Plasmodium reservoir to accelerate malaria elimination in high transmission settings: a case study of Cameroon

Study objectives
An optimal dosage of artemisia afra tea infusions is effective, safe, and well tolerated in eliminating plasmodium reservoirs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/01/2022, Faculty of health sciences institutional review board (P.O Box 63 Buea, Cameroon; +237 332 21 34; irbfhs@gmail.com), ref: 2021/159-01/UB/SG/IRB/FHS

Primary study design

Interventional

Study design
Phase II randomized controlled partial-blind parallel-group study

Study type(s)
Treatment

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

Interventions
The study is a Phase 2 randomized controlled, partial-blind, parallel-group study in plasmodium infected asymptomatic adults 18 years and older, with 8 study arms. It will use the adapted Zelen design, which has two steps in the consent process. In the first step, there is informed consent from all participants for a cohort lifestyle study. According to this consent, participants are randomized without knowledge of the detailed protocol.
In the second step, only participants from the intervention group will receive the information about the intervention and the second consent will be obtained from them. The participants who will decline to participate in an intervention will continue in the cohort study, as the control group.
Duration of study: The study duration is 35 days (5 weeks) for each participant.

Treatment groups (TG):
- TG 1: Group of 8 persons receiving A. afra infusions of 5 g/1 liter of water, 3 drinks a day, daily for 1week (7 days) (current recommendation).
- TG 2: Group of 8 persons receiving A. afra infusions of 5 g/500 ml of water, 2 drinks a day, daily for 1week (7 days) (increase concentration and decrease dose frequency).
- TG 3: Group of 8 persons receiving A. afra infusions, 5 g/1 liter of water, 3 drinks a day, weekly for 4weeks (decrease dose frequency and increase length of treatment).
- TG 4: Group of 8 persons receiving flavored A. afra infusions, 5 g/1 liter of water, 3 drinks a day, daily for1week (7 days) (current treatment with improved taste).
- TG 5: Group of 8 persons flavored A. afra infusions, 5 g/500 ml of water, 2 drinks a day, daily for 1 week (7 days) (improved taste, increase concentration and decrease dose frequency).
- TG 6: Group of 8 persons receiving flavored A. afra infusions, 5 g/1 liter of water, 3 drinks a day, weekly for 4weeks (improved taste, decrease dose frequency and increase length of treatment);
- TG 7: Group of 4 persons receiving flavored placebo infusions, 5 g/liter of water, 3 drinks a day, daily for 1week (7 days) (improved taste with no active molecule);
- TG 8: Group of 4 participants receiving regular tea placebo taken as desired, daily for 1 week (7 days) (Regular tea with no active molecule).

Randomization. The randomization method will be a permuted block randomization, with a block size of either 14 or 28 at random, and with a two-to-one allocation ratio for each active arm against two different control arms (2:2:2:2:2:2:1:1)
Blinding: Partial blind.
Data collection: Data will be captured through an observation worksheet and entered in Electronic Case Reporting Forms (eCRF).

Intervention Type
Supplement

Primary outcome(s)
Parasite load measured using qPCR on blood samples collected at baseline, 7, 14, 28 and 35 days

Key secondary outcome(s)
1. Gametocyte load measured using qPCR test on blood samples collected at baseline, 7, 14, 28 and 35 days
2. Acceptability (adherence and completion) of Artemisia afra treatment measured using participant interviews and observation of the number of days of compliance to treatment on the various treatment arms at baseline, 7, 14, 28 and 35 days
3. Safety (ASEs) of Artemisia afra treatment in participants measured using participant interviews and observation of the occurrence of any adverse events at 7, 14, 28, and 35 days

Completion date
05/11/2025

Eligibility

Key inclusion criteria
1. Student or worker of a participating university
2. Aged 18 years and above, and in good general health condition
3. Have a device (phone, tablet, etc) that will support remote visits
4. Sign written informed consent form
5. Screened positive for malaria (RDT + and qPCR +) but asymptomatic

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Have a known hypersensitivity to any ingredients of the tea
2. Currently taking a malaria drug for prevention or treatment
3. Have participated in another malaria drug trial or device in the last 14 days
4. Have a history or presence of clinically significant medical, psychiatric, or emotional condition
5. Reported diabetic

Date of first enrolment
05/04/2025

Date of final enrolment

29/04/2025

Locations

Countries of recruitment
Cameroon

Study participating centre
University of Buea
South west region
Buea
Cameroon
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Sponsor information

Organisation
Académie de recherche et d'enseignement supérieur

Funder(s)

Funder type
Government

Funder Name
Académie de recherche et d'enseignement supérieur

Alternative Name(s)
ARES

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

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?
Participant information sheet	version 1		12/04/2022	No	Yes
Protocol file	version 1		12/04/2022	No	No