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Phase I clinical trial to determine maximum tolerable dose of African Bitter Root Food Supplement

Submission date 09/05/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/05/2026	**Overall study status** Ongoing	
Last Edited 11/05/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
African Bitter Root Supplement (ABRS) is a traditional herbal remedy that has been used for many generations by communities in South Eastern Nigeria. It is made from the dried root bark of a native West African plant, combined with kaolin (a natural clay mineral) and a small amount of salt. It is distributed legally as a herbal food supplement in the UK and Europe.
Some people use ABRS with conditions such as sickle cell disease or osteoarthritis. However, so far there have been no clinical trials providing scientific evidence of therapeutic benefit. Before any research on possible health benefits can be done, we need to know the safe dose range. The aim of this study is to find the maximum tolerable dose (MTD) of ABRS, the highest dose that causes no measurable side effects. This information is essential to design future trials.

Who can participate?
Healthy volunteers aged 18 years to 90 years

What does the study involve?
The study uses a well-established method called a 3+3 dose escalation design. This means we start at a low dose and, only if it is safe, increase it step by step. Doses start at the equivalent of 12 g of ABRS per day and may increase in steps up to a maximum of the equivalent of 25 g of ABRS per day. Doses may also decrease if any side effects are observed at 12g/day, with lower doses tested in that event. Each dose level is tested in a small group of volunteers before moving to the next.
A basic physical examination will be provided by a doctor at a clinic. This checks your heart, blood pressure and a lab will run a set of standard blood tests. For women of childbearing age, the blood test includes a pregnancy test to confirm that they are not pregnant. The exam includes an ECG. The results will be given to you as soon as they are available.
You will be assigned to one dose level only. You will not take more than one dose level. You will receive two sealed tubs labelled A and B, each with 16 capsules. One tub contains ABRS and one contains a placebo (dummy capsules). You will not know which is which. You take all capsules from Tub A on one day either in front of an investigator or with the investigator on a video call. Then you wait 7 days (the washout period) before taking all capsules from Tub B, again do this

while on a video call with, or in front of, an investigator. It is important you use the tubs in this sequence: A first, then B. Capsules may be swallowed whole or emptied into water and taken as a drink. There are a lot of capsules (16) because ABRS is very weak and the capsules are mostly kaolin. Take the capsules on an empty stomach, at least 1 hour before a meal. On the 8th day, there will be a second physical examination to verify that your health has not been affected by your participation. Again, the results will be shared with you.
You will be contacted (by phone, text or email) before you start, 30 minutes after taking your dose, after 1 hour, after 1 day, and after 1 week. We will ask you a standard set of questions about how you feel. You can contact the investigator at any time.
An independent doctor reviews all safety reports from this trial to protect your interests.

What are the possible benefits and risks of participating?
We do not anticipate any direct health benefit to you from taking part. Your participation will help generate safety data that may benefit future users of ABRS and enable proper scientific research into whether ABRS has any health benefits.
ABRS has been in substantial use for many generations with no safety concerns identified. Laboratory analysis of each compound in ABRS shows that every component is well below safe limits for food. The active compounds in ABRS dissolve easily in water and are rapidly cleared from the body through the kidneys, so any side effect should resolve within 24 hours. A 7-day gap between your two doses gives an extra safety margin. If you experience any discomfort, contact the investigator immediately. We will review your situation and, if necessary, stop your participation. If you feel seriously unwell at any time, seek medical attention and contact the Principal Investigator immediately. Her number is at the end of this form: you can use the phone or WhatsApp, whichever suits you best. ABRS packaging states it must not be taken in pregnancy. There is no evidence of harm, but this precaution is standard for any substance under investigation. If you are of childbearing potential, you must confirm you are using a reliable form of contraception. If you become pregnant during the trial, stop taking the supplement immediately and tell the Principal Investigator. We recommend you notify your obstetrician, who may advise a viability scan and any additional monitoring.

Where is the study run from?
Deep Life Medical Ltd (UK)

When is the study starting and how long is it expected to run for?
May 2026 to July 2026

Who is funding the study?
Deep Life Medical Ltd (UK)

Who is the main contact?
1. Dr Emem Usoro, emem.usoro@doctors.org.uk
2. Dr Alex Deas, alex.deas@deeplifemedical.com

Contact information

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Study information

Scientific Title
A double-blind, placebo-controlled, crossover Phase I dose-escalation study to determine the maximum tolerable dose of African Bitter Root food supplement (ABRS) in healthy adult volunteers, in preparation for Phase II efficacy trials in sickle cell disease and osteoarthritis

Acronym
ABRS-P1-DOSE

Study objectives
To establish the maximum tolerable dose of African Bitter Root food Supplement (ABRS).

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design

Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Dose escalation in healthy volunteers for subsequent Phase II trial of use in sickle cell disease and osteoarthritis

Interventions
The intervention is African Bitter Root Supplement (ABRS), a herbal food supplement.
The methodology is a 3+3 dose escalation trial.

Trial setup:
1. Start the trial and enrol an initial cohort of 3 participants. A participant participates at only one dose level.
2. Assign intervention packs A and B to each participant; these are pre-randomised by the manufacturer as to which pack contains ABRS and which contains placebo.
3. Administer doses according to protocol. The participant takes all of pack A, waits the washout period (initially 7 days), and then takes all of pack B.
4. Assess safety and record dose-limiting toxicities (DLTs) within the assessment window, which is from the first dose (placebo or ABRS) to 7 days after the second dose (placebo or ABRS). Safety is assessed by the PI. All DLT events are reported to the Data and Safety Monitoring Board (DSMB) promptly.
5. The DLT assessment is performed by a SPARK Ada computer program which has the blinding information loaded but not visible to users of the program. The program is given a serial number for the intervention packs and the day on which the DLT occurred (if any). It determines whether the reported toxicity event is on a day with the placebo or a day with the ABRS for all 3 (or 6) in the cohort and recommends the escalation action.

The program uses the following algorithm to screen reported DLTs from placebo use.
1. If the reported DLT is for a participant on the placebo who has not had ABRS, then the program instructs the investigator to substitute that participant and rerun that dosage with the new participant.
2. If the reported DLT is for a participant who has used ABRS that day, it is treated as a DLT.
3. If the reported DLT is for a participant who used the placebo that day, but who has been exposed to ABRS at the dose for that stage previously, then the entire stage is repeated with

the washout period increased to 14 days, and that increased period shall be used for the remainder of the trial.
4. If a DLT occurs during the ABRS period, but the participant previously took the placebo and had a DLT during that period too, then the whole cohort of 3 should be re-run.

2. Apply a 3+3 decision at the current dose:
2.1. If there are no DLTs in the first 3 participants, escalate to the next higher dose with a new cohort of 3.
2.2. If one DLT in the first 3 participants, expand the cohort to 6 participants at the same dose.
2.3. If two or more DLTs in the first 3 participants, stop escalation and designate the previous lower dose as the MTD candidate.

3. Expanded cohort review:
3.1. Continue treatment and monitor safety for all 6 participants.
3.2. If total DLTs are 1 or fewer out of 6, escalate to the next dose.
3.3. If total DLTs are 2 or more out of 6, stop escalation and designate the previous lower dose as the MTD candidate.

4. Escalation loop and stopping:
4.1. Repeat the dose-escalation steps for subsequent dose levels until a stopping rule is met or the highest planned dose is tested.
4.2. The dose is a modified Fibonacci sequence starting at 1 g/day and a maximum of 25 g/day, with the first dose entry point in the series at 12 g/day. The series allows for de-escalation of dose downwards from 12 g if AEs occur.

5. Trial completion decision:
5.1. If the highest planned dose is completed without unacceptable toxicity, select the highest tested dose as the MTD for further study.
5.2. If the highest planned dose or stopping rule shows unacceptable toxicity, select the previous safe dose as the MTD for further study.

6. Close trial:
End the trial and document the selected dose and safety outcomes.

Intervention Type
Supplement

Primary outcome(s)
1. Maximum tolerable dose measured using 3+3 dose escalation using modified Fibonacci sequence at the conclusion of the trial

Key secondary outcome(s))
1. Immediate side effects or tolerability issues measured using report of adverse events at the conclusion of the trial

Completion date
28/07/2026

Eligibility

Key inclusion criteria

To be eligible to participate in this trial, an individual must meet all the following criteria at the time of joining the trial, in addition to not meeting any of the exclusion criteria:
1. Literate in English, able to understand the PIL, Consent and Reporting forms provided
2. Have the capacity to make an informed decision without pressure
3. Be over the age of 18 years or the age of majority, whichever is the higher, and under the age of 90 years
4. Be willing to participate in the Trial and report
5. Free of any acute health issue
6. If a participant is of childbearing potential, it shall be confirmed that the participant is on a long-acting reversible contraception (LARC) or another form of reliable contraception

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
0

Key exclusion criteria
An individual who meets any of the following criteria will be excluded from participation in this trial if they do not meet the inclusion criteria above, or are:
1. Minors meaning any person under the age of 18 or under the age of majority, whichever is the highest
2. With any drug dependency
3. In a vulnerable population (unable to give informed consent, prisoners etc)
4. Pregnant women
5. Having known allergies to medication
6. The PI's professional liability insurance excludes the USA so no participants may be enrolled who are in the USA or who hold passports from the USA

Date of first enrolment
20/05/2026

Date of final enrolment
20/07/2026

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
Deep Life Medical Ltd
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Scotland
EH21 6SY

Sponsor information

Organisation
Deep Life Medical Ltd

Funder(s)

Funder type

Funder Name
Deep Life Medical Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			11/05/2026	No	No
Participant information sheet		09/05/2026	11/05/2026	No	Yes
Protocol file		09/05/2026	11/05/2026	No	No