PARTICIPANT INFORMATION LEAFLET

TRIAL: HUMAN DOSE ESCALATION

Phase 1 Clinical Trial to Determine the Maximum Tolerable Dose of African Bitter Root Food Supplement (ABRS)

Trial Acronym	ABRS-P1-DOSE
Principal Investigator	Dr. Emem Usoro (GMC 7266847)
Sponsor	Deep Life Medical Ltd, 6 Newhailes Industrial Estate, Musselburgh, EH21 6SY, UK
ISRCTN Number	To be added once assigned.
Version	A0 — 9th May 2026

1. What is this document?

You are being invited to take part in a research trial. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information leaflet carefully. Talk to others about it if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

2. Why is this trial being done?

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 purpose of this trial is to find the Maximum Tolerable Dose (MTD) of ABRS — that is, the highest dose that causes no measurable side effects. This information is essential to design future trials.

3. Do I have to take part?

No. Taking part is entirely voluntary. If you decide not to take part, this will not affect any care or services you receive. If you decide to take part, you are free to withdraw at any time and without giving any reason, including the right during the trial to withdraw all data retrospectively.

4. Who can take part?

You may be eligible if you:

- Are 18 years of age or older (and under 90)
- Are literate in English and able to understand this leaflet and the consent form
- Are free from any acute (active short term) health condition at the time of joining
- Are willing to participate and to report any symptoms honestly

- If you are a woman of childbearing potential, you are using a long-acting reversible contraceptive (LARC) or another reliable form of contraception

You cannot take part if you:

- Are under 18 or under the age of majority in your country
- Are pregnant or have a possibility of becoming pregnancy during the week of the trial
- Have a drug dependency
- Have known allergies to medications
- Are in a vulnerable situation that affects your ability to give free and informed consent (for example, prisoners)
- Are based in or hold a passport from the USA (the PI's insurance does not cover the USA)

5. What will happen if I take part?

The trial 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.

Dose levels

Doses start at the equivalent of 12 grams of ABRS per day and may increase in steps up to a maximum of the equivalent of 25 grams 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.

What you will do

- 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 child-bearing 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 one 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.

Monitoring

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.

6. What is the placebo?

The placebo capsules look and taste the same as the ABRS capsules. They contain kaolin, salt, and dried dandelion root (instead of African Bitter Root). The packaging states it may contain a placebo. This means neither you nor the investigator will know which tub is ABRS and which is placebo — this is called double blinding, and it helps us get reliable results.

7. What are the possible risks and side effects?

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.

8. What are the possible benefits?

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.

9. Contraception

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.

10. Are there any lifestyle restrictions?

There are no restrictions on caffeine, alcohol, tobacco, or physical activity. The only request is that you take your dose on an empty stomach, at least one hour before eating.

11. What happens to my data?

All data collected about you in this trial will be stored securely on the sponsor's electronic document management system (eDMS). Your personal details (name and contact information) will be kept separate from the trial data and identified only by a reference number. Only the Principal Investigator and the sponsor's IT Manager will have access to information that identifies you.

Data will be held for 15 years in accordance with the sponsor's quality management system. The trial complies with UK data protection law. If a data breach occurs, you will be notified promptly.

Anonymised results may be published in scientific journals and presented at conferences.

12. Will I be paid?

Your reasonable out-of-pocket expenses (for example, travel costs) will be reimbursed. We cover the costs of the physical examinations directly with the clinic so you are not charged. You will not receive payment for participating.

13. Insurance and indemnity

Deep Life Medical Ltd, as sponsor, provides insurance cover for this trial. This covers any harm that may arise as a direct result of your participation in accordance with the applicable regulations.

14. Who has approved this trial?

This trial involves a food supplement, not a medicine.

The UK Health Research Authority (HRA) tool has confirmed that this trial does not require a separate ethics committee approval under current regulations. In addition, the sponsor's own ethics committee has reviewed and approved the protocol.

15. Who can I contact?

If you have any questions, concerns, or wish to withdraw:

Principal Investigator	Dr. Emem Usoro, GMC 7266847 emem.usoro@doctors.org.uk **Tel & WhatsApp: +44 7563 617 237** This is a monitored clinical team inbox, which if you call or Chat using WhatsApp, you will be able to see Dr Usoro's direct personal number, as well as the sponsor's. Either the PI or the sponsor may link in the independent doctor who provides Safety Monitoring for this research to ensure your interests are put first.
Sponsor Contact	Dr. Alex Deas PhD compliance@deeplifemedical.com

Thank you for taking the time to read this information. Please ask us anything you are unsure about before deciding.