PARTICIPANT INFORMATION LEAFLET

TRIAL: HUMAN DOSE ESCALATION

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

Trial Acronym	ABRS-P1-DOSE
Principal Investigator	Dr. Emem Usoro (GMC 7266847)
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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 Intake (MTI) of ABRS — that is, the highest dose that causes no measurable side effects or effects from overeating. 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 and able to understand this leaflet and the consent form. If you are not fluent in English, ask for this document in your own language, a translation will be provided.
- 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 or to food plants
- Are in a vulnerable situation that affects your ability to give free and informed consent (for example, prisoners)
- Are resident in, domiciled in, or a citizen or national of the USA (as the PI's insurance does not cover the USA). Additionally, no participant may take any dose while physically present in 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 medical history will be taken and a physical examination will be provided by a doctor at a clinic. The exam includes an ECG (a recording of your heart's electrical activity), blood pressure measurement, and a blood and urine test panel. If you are a woman of child-bearing age, the blood or urine test will include a pregnancy test to confirm that you are not pregnant. The results will be given to you after they have been checked by a medical doctor in the trial team.

  Please tell the investigator about any medications or supplements you take regularly. Some may need to be noted by the medical team, though there are no absolute restrictions.
- On review of your initial medical exam results, you may be asked to take additional tests, such as ultrasound imaging of your abdominal organs to assess your health before you participate.
- You will be assigned to one dose level only. You will not take more than one dose level.

  We will use a pack containing two sealed tubs, one labelled A and the other labelled B, each with 16 capsules. One tub contains ABRS and the other is a placebo (dummy capsules). You will not know which is which.
- You will be asked to 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 at least 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 so the investigator will keep tub B until you are ready for it. In some circumstances the second dose may be delayed and the examination will take place the day after whenever that second dose occurs: the investigator will confirm the timing with you.
- 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 day after you take the second set of capsules, there will be a second physical examination

Monitoring

The investigator needs to see you when you take the dose, either with you or on a video call. We will check with you 30 minutes after, 1 hour after, the day after, and 1 week after taking each dose to ask you a standard set of questions about how you feel. If you feel any adverse effect contact the investigator immediately. See Section 7 below.

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, regulatory bodies, clinical auditors or the sponsor's compliance officer 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. What happens if the medical exam finds a problem?

The purpose of the medical exam and lab tests is to detect any change that might be linked to participation, and to ensure you are healthy and eligible to participate. We are not expecting any negative change but the trial is needed to confirm that.

All medical exam and lab results from the trial's screening tests before and after you participate are reviewed by a medical doctor running the trial, and also by specialists (this may be a microbiologist or other medical scientist depending on circumstances). A doctor will discuss our interpretation of results with you and help you to understand them, their implications and your options. The discussion may be assisted by a cultural or language interpreter if we believe that would help you. If you do not understand anything, you can request that extra assistance at any time during the trial. You will also be given a copy of the actual results (lab test results, doctor's findings, etc).

If any unexpected pre-existing conditions (diseases) are detected in the screening (the medical exam or lab tests), then we will help you find a local doctor to investigate, or we may recommend further tests, or you may be offered advice in accord with established guidelines, depending on the circumstances and the severity of the condition. We will cover the cost of an initial set of diagnostic tests we specifically recommend if they are needed to understand the results we find, including if needed, the first consultation with a local doctor. Any treatment plan you decide for pre-existing conditions is a personal matter and is not covered by the trial.

If we detect a potential critical health issue, we will inform you promptly, and cover additional tests for you until the treatment options are identified, if those tests are appropriate and are what you want.

Our responsibility stops at covering the medical and lab tests we authorise. Additional lab tests may be recommended but unless we authorise them and contract with the clinic or lab to carry them out, we are not responsible for their cost. We are not responsible for the cost of treatment options you may choose, or the cost of following recommendations to address pre-existing conditions.

In the highly unexpected event that you fall ill during the trial and it is plausible that the illness is a consequence of participation, then we will cover the cost of medical treatment reasonably required to diagnose and treat that illness to the extent it is attributable to your participation in the trial, in accordance with our insurance cover.

13. 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 and lab tests directly with the clinic so you are not charged. You will not receive payment for participating.

14. 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.

15. 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.

16. 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.