Participant Information Sheet - Preoperative Patients (Group 1)

Feasibility of a novel nutritional supplement for surgical patients

We would like to invite you to take part in our research study as part of our hope to help you become stronger and help you recover from the surgical operation you will be having. Before you decide, we would like you to understand why the research is being done and what it would involve.
Please take time to read this information and feel free to ask us any questions or raise any concerns. The research is very safe and will help us to better understand if specific nutrition supplements can be taken easily by people before they have a surgical operation. The first part of the study is looking at the information that is usually collected at your usual appointments with the doctors, such a height and weight measurement, along with some additional assessments during 2 visits. As part of the study approximately 4 weeks after the initial 2 visits, you will be contacted by the researcher where we will repeat the measurements taken in the initial appointment, as well as collect a short food diary that you will have completed at home.

Purpose of the study
In previous research we have identified that people waiting to have surgical operations may require additional nutritional support. In this study we will look at the acceptability of the additional nutritional supplement to determine if these are manageable for patients to complete as part of their preparation before surgery and also other measures looking at what the body is made up of so we can see if there are any changes following consumption of the supplements. We hope that this study will inform future research to establish if specific nutrition is needed before surgery to help improve your strength and overall quality of life. The supplement is a small volume gel (65 gms) contained in a foil sachet that can be taken alongside your usual meals and contains easily digestible proteins, minerals, vitamins and extra calories.

Why have I been chosen?
You have been chosen because you are going to be having an operation in the next few weeks and meet the inclusion criteria for the study.

Do I have to take part?
No, you do not have to take part in this study. If you do not wish to take part, your decision will not affect your usual clinical care. You can withdraw from the study at any point if you change your mind after consenting. You can also consent to some but not all of the tests if you would rather.

What will happen if I decide to take part?
If you agree to participate, you will be given further information by one of the study team and you will then sign a consent form before the study begins at your usual preoperative assessment.
We will arrange with you for the additional assessments to take place and your travel expenses will be paid for.
You will be given a unique study number so that your data remains anonymous to anyone else.

What will be involved?

The study will involve collecting routine information as part of your usual care such as your diagnosis and the planned treatment you will be undergoing. Once collected in full the data will be extracted from your patient record and anonymised so that it cannot be traced back to you as an individual.

The nutritional supplements will not be available once the study has been completed but you will have received education about your nutrition that will be useful after the study is completed.

Part A of the study

You will visit our laboratory at Leeds Beckett campus on 2 occasions for part A of the study and complete the following tests after you have had an overnight fast and have refrained from strenuous activity or consumption of alcohol the day before.

- **Taste test of the nutritional gel and completion of taste questionnaires – (5 mins)** – this will help us to see if you are able to take the gel and record how it tastes to you. This assessment will be done once only. If you are unable to or do not like the gel you will not be asked to continue to take them. If you are able to continue to take the gels you will be asked to take 2 each day for a period of 4 weeks.
- **Eating a breakfast meal with or without the gel (20 minutes)** -you will be asked to also eat a bowl of porridge to see if you can take the gel alongside your meals and we will document your appetite during your breakfast at regular intervals in a questionnaire. One meal will be with the gel and one meal will be without the gel. You will need to come to our laboratory twice to have the breakfast meals a week apart.
- **Dietary intake (10 minutes)–** this will be a short conversation with the team who will ask about what you had to eat and drink the previous day. You will be shown how to complete a 3-day food diary that will be assessed in week 3 and this will be collected at a visit to the campus following completion of the 4 weeks.

On your second visit once you have finished your breakfast meal, we will measure your physical health by the following methods:

- **Measurement of handgrip strength (7 mins)** – using a small handgrip device we will ask you to squeeze 3 times and record the results. This measure tells us about the functionality of the muscles in your arm and is a very useful indicator of wellness.
- **Get up and go test (10 minutes)** – this test is to understand your baseline fitness and will tell us a lot about how well you may be at the time of the assessment.
- **Measuring body composition with Bio Electrical impedance machine (10 mins) –** this is a machine that you will be required to stand on, it measures what your body is made of.

After you have completed these assessments we will discuss:

- **Dietary intake (15 minutes)** – we will explain how to fill out a food diary for three days during the third week of you taking the supplements. This diary will be collected when you return for your third visit to the Leeds Beckett University campus.
- You will be given sachets of the gels to take twice a day, at breakfast and lunch for 4 weeks.

Part B of the study

Third visit (after 4 weeks of taking the nutritional supplement):

- **Dietary intake (10 minutes)–** This will help us to understand any changes to your eating and drinking during the study. We will collect this record of your dietary intake will occur 1 time looking at 3 days of your food intake in week 3.
- **Assessment of gels consumed, and sachets saved over the four weeks –** You will be asked to return any unwanted gels to the laboratory**.**
- **Measurement of handgrip strength (7 mins)** – using a small handgrip device we will ask you to squeeze 3 times and record the results. This measure tells us about the functionality of the muscles in your arm and is a very useful indicator of wellness.
- **Get up and go test (10 minutes)** – this test is to understand your baseline fitness and will tell us a lot about how well you may be at the time of the assessment.
- **Measuring Body composition with Bio Electrical impedance machine (10 mins) –** this is a machine that you will be required to stand on, it measures what your body is made of. It can tell us if any changes have happened from the beginning of the 4 weeks and starting to have the additional nutritional supplements and the end.

What are the possible benefits of taking part?

This study will help us learn about if these supplements can be tolerated for a period of time and any improvement in your general health whilst you are preparing for your surgery. It is also possible the nutritional supplementation will have had no benefit and therefore your participation will be very helpful to describe its usefulness.

What are the possible risks of taking part?

This is a safe study but some parts may feel more difficult to do and these are listed below:

- Being asked to recall your dietary intake relies on memory and may cause you frustration if you struggle with this.
- Being asked to complete questionnaires may also cause frustration and survey fatigue during your visit to the Leeds Beckett University campus, but we will help you complete these.
- Completing the get up and go test requires you to sit and stand up for a continued short period and you may feel tired afterwards
- Assessing handgrip strength will also require you to hold and grip a piece of equipment (3 times) which if not done correctly may cause discomfort.

Whilst all of the measures above may cause some difficulty you can at any point stop any of the measures if you choose not to continue.

The Leeds Beckett University campus follows government COVID19 guidance on social distancing and personal protective equipment will be utilised by the research team and available for you throughout your visit.

Indemnity insurance in the event of an adverse event during participation is provided by Royal and Sun Alliance who are the insurance brokers for The University of Leeds.

Confidentiality

All information which is provided to the study by you will be kept strictly confidential. People who do not need to know who you are will not be able to see your name or contact details. Once the study is completed, we will keep your data to check some of the results and the reports will be written so nothing can be linked back to you as an individual.

What will happen to my information?

The University of Leeds is the sponsor for this study and following your consent, the information you and the other participants provide will eventually be used as part of a written of educational report (PhD thesis). These are also likely to be presented and possibly published as research including being used as the basis for a larger study in the future. You GP will be informed of your participation in this study.

Data Storage

Consent forms will be kept at the St James's University Hospital site. This will then be stored in a locked cabinet in the hospital building and allow access for the main study coordinator.

All of the information generated during the study will be given a number that will be used to refer to the documents contained data generated during the studies so your personal details will remain private. Only the unique study number will be entered onto the computer database for the assessments and storage of results. Assessment data will be stored on secure, encrypted NHS computer drive and also on secure password protected Leeds Beckett University server. Assessment data will be anonymised with only individual study number and will be stored for 5 years. We would like to be able to identify data we have collected for participants. Only the study team Chief Investigator and coordinator will have access to the stored data after study completion. The stored data from the study will be anonymised and may be shared with other researchers after the study has ended but only with consent from you as the participant.

Further information can be found here:

https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf.

https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/09/HRA-transparency-wording.pdf

Ethical approval

The study has been given ethical approval by NHS Ethics. Your general practitioner will be informed of your participation in the trial.

Can I see the results?

We will not be routinely sending results to individuals however if you specifically request your results this can be arranged by informing the study co-ordinator (see below)

What if I have a problem with the study?

If you have a problem or any concern about any aspect of this study, please do contact a member of the research team using the details below or University of Leeds.

Concerns and contact details

If you have any concerns with regard to the way your personal data is being processed or have a query with regard to this Notice, please contact our Data Protection Officer at dpo@leeds.ac.uk Our data controller registration number provided by the Information Commissioner's Office is Z553814X

Researcher details:

Mrs Angela Windle is an advanced clinical practitioner at Leeds Teaching Hospitals Trust and works in general surgery. Angela will be the study co-ordinator for this feasibility study.
Email: angela.windle@nhs.net

Supervisor details:

Mr Dermot Burke is the Principal Investigator and research supervisor. Mr Burke is an associate professor of clinical surgery at The University of Leeds and a consultant colorectal surgeon at Leeds Teaching Hospitals Trust.
Email: d.burke@leeds.ac.uk

If you wish to make a complaint about the study then please contact

Patient advice and Liaison services (PALS)
St James's University Hospital
Beckett Street
Leeds
West Yorkshire
LS9 7TF
Tel: 01132067168
Email: patientexperience.leedsth@nhs.net

Or you can contact the University of Leeds Sponsor

Mrs Clare Skinner
Faculty of Medicine and Health Research Office
Level 9, Room 9.29
Worsley Building
University of Leeds
Leeds
LS2 9NL
Telephone: 01133434897
Email: governance-ethics@leeds.ac.uk

Thank you for reading this information sheet. Please speak to any of the research team detailed above if you have any further questions.