

Participant Information Sheet

**THE EFFECT OF ENZYME RICH MALT EXTRACT IN TREATMENT OF IRRITABLE BOWEL SYNDROME (IBS)**

**Part 1**

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being carried out and what it would involve for you. Please talk to others about the study if you wish.

**Part 1** of the information sheet tells you the purpose of the study and what will happen if you choose to take part. **Part 2** gives you more detailed information about the study.

Please ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

Irritable bowel syndrome is a common condition, which causes symptoms of abdominal pain, bloating and altered bowel habit. Conventional treatment is frequently unsatisfactory.

The cause of irritable bowel syndrome (IBS) is unknown, but it has been suggested that many of the symptoms result from undigested carbohydrates reaching the large bowel (colon). When this happens, the gut bacteria living in the large bowel can ferment undigested food producing chemicals that cause disease. These chemicals can be detected in both blood and urine. It has been shown that reducing the number of certain carbohydrates within the diet can improve the symptoms of irritable bowel syndrome (IBS) for some patients.

**What medication is being tested?**

The study does not involve a medicine. We wish to explore whether giving a food supplement called enzyme rich malt extract (ERME) that contains a high concentration of enzymes that digest carbohydrates will improve symptoms of IBS. ERME is a by-product of the malting process, in which cereal grains (like barley) are dried, commonly for making beer. It is sweet, palatable and easily available at relatively low cost and has been used as a foodstuff in baking and cookery for many years.

**Why have I been invited to take part in this study?**

We are inviting you to take part in this study because your clinician has diagnosed you with symptoms of irritable bowel syndrome.

**Do I have to take part?**

It is entirely up to you to decide whether to join the study. A decision not to take part would not affect the standard of care you receive. If you do decide to take part and then change your mind, you may withdraw at any time although we would ask for your permission to include information collected up to that point in the study.

If you are interested in taking part in this study and would like further information please return the enclosed reply slip in the prepaid envelope supplied. A member of the research team will then contact you to discuss the study further.

Following the conversation and if you would like to proceed with the study a member of the research team will arrange to contact you again at a time that is convenient for you. During this conversation will ask some initial questions over the telephone to see if you might be suitable to take part. We need to ask you a few questions about your health and any medicines you may be taking and complete two short health questionnaires. We estimate this will take around 10 minutes.

**What will happen to me if I take part?**

Following the initial screening phone call, if we think your IBS symptoms are suitable for the study we will invite you to attend a research clinic appointment. This will be at the Joint Clinical Research Unit (JCRF) Swansea Bay University Health Board (previously ABMU HB), with the study doctor and research team to discuss the study further and, if you agree to take part at that time, we will then ask you to sign a consent form.

Reasonable travel expenses will be provided for all study visits.

**Screening to assess if you meet the entry requirements for the study**

During the clinic visit we will ask you some questions about your IBS symptoms your current medication and questions about your medical history. We will also need to check your previous blood test and stool test results which were performed at your recent hospital appointment. If the tests have been performed more than 12 months ago, we will need to repeat these. The tests will be performed in the JCRF by one of the research team.

Additionally, we will ask you to provide a urine samples at the start and the end of the study so that we can see if there are any changes. These samples are for the purpose of this study and we will not reveal any other information about you. Your samples may be sent to external laboratories for analysis and will only be identifiable by a unique study number that will be allocated if you join the study. All samples will be destroyed after the research has been completed.

Patients agreeing to take part in the study will be randomly assigned to take either 30mls of enzyme rich malt extract (ERME) each day or a similar product, also made from barley, that tastes the same but that does not contain the active ingredient (we call this a placebo). You have an equal chance of being allocated ERME or placebo and neither you nor the research team will know which arm of the study you are assigned.

ERME is a yellow-brown syrup and 30mls of product is approximately two tablespoons. We would ask you to take 15mls (one tablespoon) at breakfast time, and another 15mls (one tablespoon) with your last meal of the day, for a period of six weeks. If you wish you can spread on toast or just take from the spoon. ERME is sweet and most patients find it very palatable. However, before you agree to take part in the study we will offer you an opportunity to taste the product so that you are able to make a decision about whether you would find it acceptable.

You will also be asked to undertake fortnightly symptom questionnaires (see table 1 below) and our research nurse can complete these over the telephone with you. The questionnaires will ask about your symptoms that are affecting you at that time.

After 6 weeks, you will come back to the research clinic for the final visit where we will repeat some of the investigations undertaken at visit 1. You will stop taking the product at this time.

Two weeks after the 6 week final visit a member of the research team will contact you again by telephone to assess your IBS symptoms and to complete the questionnaires for the final time. After this, your involvement in the study will be completed. Once the study is completed and information analysed we will provide you with a summary of the results. If you would like to discuss the results in more depth you can contact a member of the research team.

Table 1 summary of study schedule

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Description | Pre Screen | Visit 1 Clinic | *Telephone*  *call 2 weeks* | *Telephone call 4 weeks* | Visit 2 Clinic  6 weeks | *Telephone call 8 weeks* |
|  |  |  |  |  |  |  |
| Consent |  | Yes |  |  |  |  |
| Inclusion/exclusion | Yes |  |  |  |  |  |
| Demography |  | Yes |  |  |  |  |
| Past medical history | Yes | Yes |  |  |  |  |
| Blood test FBC | Yes\* |  |  |  |  |  |
| Stool sample | Yes\* |  |  |  |  |  |
| Randomisation |  | Yes |  |  |  |  |
| Intervention ERME/Placebo |  | Yes |  |  |  |  |
| Questionnaires  Rome IV  Mal fermentation  IBS QoL  IBS Severity Score  Nijmegen | Yes  Yes | Yes  Yes  Yes | Yes  Yes | Yes  Yes | Yes  Yes  Yes  Yes | Yes  Yes |
| Urine sample |  | Yes |  |  | Yes |  |
| Adverse events |  | Yes | Yes | Yes | Yes | Yes |

* Repeat FBC blood test if last test was over 12 months ago
* Repeat faecal calprotectin stool test if last test was over 12 months ago

**What are the possible disadvantages and risks of taking part?**

We do not know of any disadvantages or risks of taking part. It is possible that some patients could experience slightly looser bowel motions although we believe this is unlikely at the dose of product being advised.

If you need to have a repeat blood sample taken this occasionally may cause some minor discomfort and slight bruising at the sampling site. The blood sample is 4ml (approximately one teaspoon full).

If you need to provide a stool sample the study nurse will explain how to perform this, provide you with the necessary equipment and instruct how to return the specimen to us.

**What are the possible benefits of taking part?**

It is possible that ERME will improve your symptoms. If this is the case and if ERME becomes commercially available this may be a treatment option for your symptoms.

Unfortunately, because ERME is not currently being manufactured commercially, we cannot continue to provide it to you once the study has ended.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2 of this information sheet.

**Will my taking part in this study be kept confidential?**

Yes. We will follow standard ethical and legal practice and all information about you will be treated in confidence. The details of how we will do this are given in Part 2.

If the information in Part 1 of this sheet has interested you and you are considering taking part, please read the additional information in Part 2, before making any decisions.

**Part 2**

**What will happen if I don’t want to carry on with this study?**

You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you decide to withdraw from the study we will use the information and samples that we have collected from you up to the point of your withdrawal unless you ask us otherwise.

In the unlikely event that you lose your capacity to consent during your study involvement any information or samples collected will be destroyed and not used toward the study analysis.

**How will we use information about you?**

We will need to use information from you and your medical records for this research project.

This information will include your initials, NHS number, Name, contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

All information that is used for the study analysis will have a unique numerical code so that your privacy is protected and you cannot be identified in any reports or publications.

**What are the choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information at [www.hra.uk/information-about-patients/](http://www.hra.uk/information-about-patients/) asking the research team who are running this study, the NHS Health Research Authority leaflet (included at the end of this document) which explains how health researchers use your information and from: [abm.rd.@wales.nhs.uk](mailto:abm.rd.@wales.nhs.uk)

**What if there is a problem?**

If you are unhappy about this study, you can talk to a member of the research team or the Research Adviser in the hospital’s Research and Development (R&D) Unit. Contact details are provided at the end of this information sheet.

If you remain unhappy with the treatment or service you have received from the Joint Clinical Research Facility (JCRF) you are entitled to make a complaint, have it considered, and receive a response

You can do this verbally by contacting the Patient Experience Team at the hospital by writing to them at Patient Experience Office, Swansea Bay Headquarter, One Talbot Gateway, Baglan Energy Park, Baglan Port Talbot, SA12 7BR by phoning them on 01639 684391 or by emailing them at patient.experience@wales.nhs.uk

If you remain unhappy following this and you wish to complain formally, you can do this by contacting the [Parliamentary and Health Service Ombudsman](http://www.ombudsman.org.uk/), who is independent of the NHS and government, at 0345 015 4033.

You may also find help online at:

<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx>

**Will my taking part in the study be kept confidential?**

Information we collect from you as part of the study will be recorded on paper and/or on a computer database. The research team at the hospital will each have unique passwords to access the database. You will be given a numeric code, unique to this study, and this code will be used on the samples, case record file and the database rather than your name, so you cannot be immediately recognised from the information.

The code linking your name with the information we collect during the study will be kept in separate locations with restricted access.

If you join the study, some parts of your medical records and data collected for the study will be looked at by one or two authorised people from the Research and Development Department at the hospital and a study monitor from Ateria Health Ltd the Sponsor. This is because the R&D Department has a duty to check that the research is being carried out correctly as does the sponsor. These individuals will have a duty of confidentiality to you as a research participant.

**What will happen to the results of the research study?**

We intend to publish the results of the study in reports and specialised medical journals. The results of the study will only be described as a summary of the whole group experience and not of individuals. You will not be identifiable in any report.

**Who is organising and funding the research?**

The study will be undertaken and managed by the JCRF, ILS2 Swansea Bay University Health Board and is being funded by Ateria Health Ltd, a small commercial company who are covering the cost of any additional samples as described in this information sheet, research nursing and other staff.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This is to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favorable opinion by to be inserted.

**Further information and contact details**

If you would like further information about the study, please contact:

Mr. Andrew Cunningham, at Swansea Bay University Health Board on 01792 530819

Or Lucy Barlow one of our Lead Research Nurses on the JCRF on 01792 530819.

**Thank you for taking the time to read this information**



**This document explains how health researchers use information from patients. If you are asked to take part in research, you can ask what will happen in the study.**

**What is patient data?**

When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It’s important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

**What sort of patient data does health and care research use?**

There are lots of different types of health and care research.

If you take part in a clinical trial, researchers will be testing a medicine or other treatment. Or you may take part in a research study where you have some health tests or answer some questions. When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. During the study you may have blood tests or other health checks, and you may complete questionnaires. The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

In other types of research, you won’t need to do anything different, but the research team will be looking at some of your health records. This sort of research may use some data from your GP, hospital or central NHS records. Some research will combine these records with information from other places, like schools or social care. The information that the researcher

information from other places, like schools or social care. This information the researcher collects from the health records is research data.

**Why does health and care research use information from patients?**

In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than other. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient’s health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

**How does research use patient data?**

If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudo-anonymised data. For example, your blood test might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

In other research, only the doctor copying the data from your health records will know your name. They will replace your name with a code number. They will also make sure that any other information that could show who you are is removed. For example, instead of using your date of birth they will give the research team your age. When there is no information that could show who you are, this is called anonymous data.

**Where will my data go?**

Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. This may involve other hospitals, or universities or companies developing new treatments. Sometimes parts of the research team will be in other countries. You can ask about where your data will go. You can also check whether the data they get will include information that could show who you are. Research teams in other countries must stick to the rules that the UK uses. All the computers storing patient data must meet special security arrangements. If you want to find out more about how companies develop and sell new medicines, the Association of the British Pharmaceutical Industry has information on its [website.](http://www.abpi.org.uk/)

**What are my choices about my patient data?**

* You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study.
* In some studies, once you have finished treatment the research team will continue to collect some information from your doctor or from central NHS records over a few months or years so the research team can track your health. If you do not want this to happen, you can say you want to stop any more information being collected.
* Researchers need to manage your records in specific ways for the research to be reliable. This means that they won’t be able to let you see or change the data they hold about you. Research could go wrong if data is removed or changed.

**What happens to my research data after the study?**

Researchers must make sure they write the reports about the study in a way that no one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it.

Usually your hospital or GP where you are taking part in the study will keep a copy of the research data along with your name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

If you agree to take part in a research study, you may get the choice to give your research data from this study for future research. Sometimes this future research may use research data that has had your name and NHS number removed. Or it may use research data that could show who you are. You will be told what options there are. You will get details if your research data will be joined up with other information about you or your health, such as from your GP or social services.

Once your details like your name or NHS number have been removed, other researchers won’t be able to contact you to ask you about future research. Any information that could show who you are will be held safely with strict limits on who can access it.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

**Will the use of my data meet GDPR rules?**

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better. When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a ‘legitimate interest’ in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of ‘a task in the public interest’. If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

**What if I don't want my patient data used for research?**

You will have a choice about taking part in a clinical trial testing a treatment. If you choose not to take part, that is fine.

In most cases you will also have a choice about your patient data being used for other types of research. There are two cases where this might not happen:

1. When the research is using anonymous information. Because it’s anonymous, the research team don’t know whose data it is and can’t ask you.
2. When it would not be possible for the research team to ask everyone. This would usually be because of the number of people who would have to be contacted. Sometimes it will be because the research could be biased if some people chose not to agree. In this case a special NHS group will check that the reasons are valid. You can opt-out of your data being used for this sort of research. You can ask your GP about opting-out, or you can [find out more.](https://www.hra.nhs.uk/information-about-patients/)

**Who can I contact if I have a complaint?**

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner’s Office (ICO) ([www.ico.org.uk](https://ico.org.uk/)  or 0303 123 1113).