GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

Participant Information Sheet

THE EFFECT OF ENZYME RICH MALT EXTRACT (ERME/JUVIA 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 symptoms. These chemicals can be detected in both blood and urine. Reducing the number of certain carbohydrates within the diet can improve the symptoms of irritable bowel syndrome (IBS) for some patients.

What is being tested?

The study does not involve a medicine. We wish to explore whether giving a food supplement called JUVIA will improve symptoms of IBS. JUVIA is an enzyme rich malt extract (ERME) that contains a high concentration of enzymes that digest carbohydrates that aim to improve symptoms of IBS. ERME is a by-product of the malting process, in which cereal grains (like barley) are dried. It is sweet and easy to

drink.

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, they 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.

The total duration of the study is 4 weeks.

What will happen to me if I take part?

Following the initial screening phone call, if we think you meet the criteria to be included in 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 ABMUHB), 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 check previous blood and stool tests that have been undertaken from your medical notes. We will ask that you provide a stool sample before you commence JUVIA (ERME) and again at 4 weeks when you complete the study. The study nurse will instruct you on how to collect the stool sample. This is a very simple procedure. We will also ask you to provide a urine sample at your first and last clinic visit.
All subjects will be asked to take a total of 40mls of enzyme rich malt extract (ERME) each day for 4 weeks (20mls two times a day). Three x 450 ml bottles of JUVIA will be supplied at visit 1, which should be stored at room temperature together with a measure to ensure the correct amount.

JUVIA is a yellow-brown syrup 20mls of product is just over a tablespoon (we will supply a measuring cup). We would ask you to take 20mls at breakfast time, and another 20mls with your last meal of the day, for a period of four weeks. If you wish, you can just take from the spoon or add to yoghurt, cereal, or juice. Do not mix with anything hot or drink a hot drink at same time. We recommend that you drink a glass of water after taking the syrup.

You will also be asked to undertake symptom questionnaires at your first visit, two weeks after starting the ERME/JUVIA (table 1 below), and at your final visit at 4 weeks. The research nurse can complete these with you over the telephone at 2 weeks if you prefer. The questionnaires will ask about your symptoms that are affecting you at that time.

After 4 weeks from the start of the study, you will need to come back to the research clinic for the final visit where we will repeat some of the investigations undertaken at visit 1 (urine and stool sample). You will stop taking the product at this time.

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***	***Visit 4 weeks***
Consent			Yes		
Inclusion/exclusion	Yes				
Demography			Yes		
Past medical history	Yes		Yes		
Stool sample			Yes		Yes
Intervention ERME (JUVIA) Dispensed			Yes		

Questionnaires Rome IV Mal fermentation IBS QoL IBS Severity Score Nijmegen	 Yes Yes		 Yes Yes Yes	 Yes Yes	 Yes Yes Yes
Urine sample			Yes		Yes
Adverse events			Yes	Yes	Yes

What are the possible disadvantages and risks of taking part?

Some patients could experience slightly looser bowel motions although we believe this is unlikely at the dose of product being advised. Due to the products activity you may experience some slight worsening of symptoms during the first few days but this should settle quickly, and it is important that you continue taking the product twice daily. If you feel this is not possible, please contact the study nurse.

Collecting 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. This is a very simple procedure. The research nurse can also explain this during the initial telephone conversation.

What are the possible benefits of taking part?

It is possible that JUVIA will improve your symptoms.

JUVIA is the name given to the product that is now available commercially as a food supplement. ERME is the name of the active ingredient given to the preparation of malt from Barley grains.

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.

If you decide to participate in the study, we inform your General Practitioner as a matter of courtesy.

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 for ongoing management of your irritable bowel syndrome. 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 ensures that you will not be identified in any reports or publications.

In respect of urine samples, these will be analysed at Brunel University and stool samples will be analysed at Microba Laboratory in Brisband, Australia. All samples will have a unique research number, which means the laboratories do not have any information about you or are able to identify you in any way. Samples will be stored initially within the Joint Clinical Research Facility and then batched and sent to the respective laboratories as above; access will be available to personnel undertaking the analysis of the samples.

If you withdraw from the study, your samples collected up until that date will be processed unless you request that they be destroyed and not analysed.

A chain of custody will document all samples store and dispatched to the relevant laboratory. Each laboratory adheres to Good Clinical Laboratory Practice regulations,

which governs all such samples. Samples once analysed will be destroyed by the respective laboratory in accordance with regulatory procedures.

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, unless you ask otherwise.

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/ 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: SBU.RandD@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, 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 available only to study staff.

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 Joint Clinical Research Facilities, 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 Wales Research Ethics Committee 6.

Further information and contact details

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

Natalie Blytt-Jordens, Senior Research Nurse 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.

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?

DPR 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.

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 or 0303 123 1113).