PATIENT PARTICIPANT INFORMATION AND

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Efficacy of Kfibre™ in combating Gastroesophageal Reflux Disease -Preliminary Human Clinical Study

Chief Investigators:

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Introduction

Gastroesophageal reflux disease (GERD) is a condition that affects around 20% Australians and causes drastic reduction in quality of life. GERD is symptomatically referred to as heartburn or reflux disease because the acidic stomach content travels backwards towards the oesophagus and the feeling of acidity is the major symptom. There is a large body of evidence to indicate significant health problems associated with GERD. These include lack of quality sleep, dysphagia, and oesophageal cancer in severe cases. Current treatment for GERD mainly consists of proton pump inhibitors (PPI). While PPI work well in over half of the GERD patients, there is a refractory group (30%) that needs effective alternative therapies.

Approach:

In order to test an alternative GERD treatment, a clinical trial will be conducted using K-fibre™ compared to a placebo of insoluble crystalline cellulose. This is a food grade fibre (Agri Food Ingredients (N G Alexander & Co Pty Ltd) Suite 15, 828 High St. Kew East VIC 3102; www.agrifi.com.au) and is used as a food fibre as well as an excipient in the manufacture of pills. The study will be conducted in Launceston by doctors in association with gastric clinics. A Research Associate will be employed to undertake the organisation of the trials and collection and collation of results.

Aim of the research study

- To determine if Kfibre™ can control the symptoms of medically diagnosed GERD
- To publish the results to enable independent review and reference to the health properties and thus validate any further investment costs for future larger or multiple human studies that would be needed for a formal health benefit claim to be made

Significance of the planned project

This study will identify potential novel nutritional therapy for GERD

Inclusion Criteria:

- Male or Female
- Ages 18-75

- Heartburn and/or regurgitation at least 3 times a week during the 7 day run- in period prior to randomization.
- Able to read, understand, and complete study questionnaires and record
- Able to understand the study procedures and sign informed consent
- Able to comply with all study requirements

Exclusion Criteria:

- Subjects with Barrett's esophagus, non-erosive reflux disease, EE grades A or B, or peptic stricture on endoscopy
- Subjects with previous upper gastrointestinal surgery
- Subjects with clinically significant underlying other health issues
- Helicobacter pylori positive
- Clinically significant GI bleed within the last 3 months
- Esophagitis not related to acid reflux
- Bleeding disorder
- Zollinger-Ellison, achalasia, esophageal varices, duodenal/gastric ulcer, upper gastrointestinal malignancy
- Women pregnant or lactating
- Concomitant medications such as PPI because the absorption rates may be altered for those medications requiring a certain saturation level to be effective.

Where will the study be conducted?

The study will be conducted at First Point Healthcare medical centre managed by Dr Jehan Phillip.

Recruitment:

You will be enrolled in the study while attending the clinic. Subjects with self-reported GERD will be administered a GERD-HRQL (health related Quality of Life) and questionnaire and if you score less than 3 will be offered enrolment in the study. In other words, people with mild to moderate heartburn will be enrolled. You will be given information on the study as per the Ethics Application.

Exclusion criteria listed above will be strictly implemented.

Treatment:

You will be assigned into Treatment Groups. The study will be double blind with neither the patient or the Doctor and staff administering the study knowing which people are receiving the treatment or placebo control.

You will be given a 150 gm container of test insoluble fibre or placebo with instructions on use. Patients will be instructed to stir one heaped teaspoon into a glass of water in the morning after food in the morning and night, to drink it immediately in suspended form. After 3 weeks treatment you will return to the Clinic for assessment and be requested to return the unused portion of the fibre to validate consumption.

What data will be collected after enrolment to the study?

Day 1: Informed consent- Age, sex, smoking status, medical history, BMI and vital signs.

At enrolment validated GERD-HRQL questionnaire will be administered by the participating GP. It has both composite score plus individual symptoms assessment (nine questions reported in a scale of 0 to 5). The overall score will be a maximum of 75 (the higher the score, the more the severity of GERD). The total time required to administer the questionnaire would be 1-2 minutes. The questionnaire has been designed to get specific data about heartburn through heartburn score (maximum of 30) and regurgitation through regurgitation score (maximum 30).

Day 20: After 3 weeks treatment the validated GERD-HRQL questionnaire will be administered again by your GP. At the conclusion of the study the research team will analyse the GERD-HRQL questionnaire data and correlate treatments against symptom scores.

What tests will be performed?

Your answering of questionnaire will be main analysis. No tests will be performed.

Which test results will be given to you?

All the results of this study will be analysed and presented as group data only. These results will be published in scientific medical journal(s) and be discussed at national and international conferences. A summary of results will be available at the end of the study and be provided to you on request. If you would like to know your individual results please contact your clinician.

Confidentiality

All data will be treated in the strictest of confidence. The information that will be collected will only be used for the purpose of this study. Records identifying you will not be made publicly available. If the results of the trial are published in a scientific medical journal, your identity will remain confidential.

Risks and discomforts

We don't expect any risks or discomfort but if you feel any discomfort from consuming the product, please contact Dr Jehan Phillips immediately

Costs

Participation in this trial will not result in any costs for you and there is no payment for participation in this study.

Participation

Your participation is voluntary and you may withdraw at any time.

Withdrawal

If you choose to withdraw at any stage, you may request that any, or all, of your data collected for the purpose of this project be destroyed. Any such request will be complied with.

Contact and further information

If you have a question about this study, or would like more information kindly contact

Dr Raj Eri: (03) 6324 5467 or rderi@utas.edu.au, *or*

Your GP Dr Jehan Phillips who recruited you for the study

This study (application number H) has been approved by the Human Research Ethics Committee (Tasmania) Network in accordance with the National Health and Medical Research Council's guidelines.

If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the Executive Officer (phone 03 6226 6254) of the Human Research Ethics Committee (Tasmania) Network. The Executive officer can direct participants to the relevant Chair that reviewed the research.

Thank you for your time.

CONSENT FORM

Title of Project: Efficacy of Kfibre™ in combating Gastroesophageal Reflux Disease Preliminary Human Clinical Study.

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1. I acknowledge that the nature, purpose and contemplated effects of the project so far as it affects me, have been fully explained to my satisfaction by the research worker and my consent is given voluntarily.

2. The details of the procedure proposed have also been explained to me, including the anticipated length of time it will take. I understand that my involvement means a maximum of 3 weeks follow up.

3. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me

4. I have been given the opportunity to have a member of my family or friend present while the project was explained to me.

5. I am informed that no information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

6. I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health. I also understand that I am free to withdraw from the project at any stage and withdraw any of my data that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.

7. I understand that I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.

8. I understand that the trial will be conducted in accordance with the latest versions of the National Statement on Ethical Conduct in Human Research 2007 and applicable privacy laws.

9. I would like my GP to be informed about my participation in this trial.

Name of GP: Dr Jehan Phillips

Name of participant _____

Signature of participant_____ Date _____

10. I have explained this project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator _____

Signature of investigator _____ Date_____