Subject Information and Consent Form

Study Title: To Evaluate the Effect of Itopride HCl on gastric emptying and accommodation in patients of Functional dyspepsia

Physician:

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Introduction

You are being asked to participate in a clinical study. Before you decide if you want to take part, you should understand the purpose of the study and what is expected of you. This consent form will give you information about the study. If you decide to take part, you will be asked to sign and date this consent form and you will be given a copy of the signed form.

Purpose

The study is being conducted to evaluate the effect of Itopride on

I) The rate of stomach emptying after taking food,
II) The ability of stomach to expand after taking food
III) Maximum tolerated amount of nutrient drink.

Itopride is an established and well tried medicine that is in use world over for patients like you. You will be asked to take 2 tablets three times a day, 15 to 30 minutes before each meal.

Study Details

The study will be carried out for a period of 6 weeks.
In the first week: you will be subjected to the following test
Blood test Routine blood test include CP, creatinine, LFTs, ECG and Pregnancy test if necessary
Drinking capacity test (you will be asked to drink a nutrient liquid up to your maximum tolerance
Tc 99 test you will be given an injection and a glass of nutrient liquid to drink followed by estimation of stomach volume by a camera. This test is similar to test done for heart diseases
13 C octanoic acid test In this test you will eat a breakfast consists of two bread pieces of bread with butter, scrambled egg mixed with Octanoic acid and a glass of orange juice. You will be asked to breath out in two test tubes every 15 minutes for 4 hours.

After the completion of tests your doctor will provide you with the medicine and the instructions on its use. You will receive one of the two treatment regimens. You may be given a treatment regime that contains placebo tablets. Placebo tablets will not contain any active or effective medicine.

The effectiveness of the drug will be checked based on your personal experience and change in your symptom severity assessed by a pre- designed questionnaire. The findings will be recorded in the Case report Forms. You will be responsible for following the treatment instructions provided to you by your physician.

Potential Benefits/ Compensation

The information collected in this study will provide a better understanding of treatment options available to treat functional dyspepsia. This study will evaluate comprehensively your stomach function. You will not be paid for your participation in this study.

Risks and possible adverse effects

You as a woman will not be eligible to participate in the study if you are pregnant or can get pregnant unless effective measures of contraception are taken (use of oral contraceptive pills or the partner uses condoms). Similarly, you will not participate in the study if you are breast- feeding your child.

Although, the study medication is used extensively for the symptoms of indigestion, however, you may experience side- effects with the medication. The observed incidence of side- effects is as low as 2.4% and of these the main side- effects observed include diarrhea, constipation, abdominal pain, nausea, dizziness, headache, tremors.

In the case of any side effect, you should immediately contact your physician, the contact details of whom is given in this form.

Voluntary Participation/Withdrawal

Your participation is completely voluntary and you can choose to stop participating at any time. Your physician, the Independent Ethics Committee (IEC), a Regulatory Agency may also decide to stop the study at any time.

Your willingness to participate in the clinical study, and thus contribute to success, has to be confirmed by you in writing by signing the declaration of the consent form.

Subjects Responsibility

It will be your responsibility to take the prescribed medicine regularly and in a manner advised by your physician. You are required to visit the doctor on scheduled date and provide correct information regarding your symptoms, use of study medication as well as other medications.

Release of Medical Information, and Confidentiality and Authorization

Your confidentiality will be protected to the extent required by applicable laws and regulations. Your information may also need to be disclosed to regulatory authorities, or an Independent Ethics Committee (IEC) if required by local law/regulations. Your medical information provided will be limited to the data necessary for the study. The results of this study may be presented at meetings and in publications.

Contact Information

If you have any questions about this study, please ask your physician.
If you have questions about your rights as a study subject, you may contact:

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Declaration of Consent

- ✓ I agree to take part in this study. I have read and understood this informed consent and all of my questions have been answered. I understand that I can withdraw my participation at any time.
- ✓ I understand that I will receive a copy of this signed and dated consent form.
- ✓ By signing this form I have not given up any of the legal rights that I would have as a participant in this study.

_____

Patient Name (print)

_____

Patient Signature Date

_____

Signature of Person Explaining Informed Consent Date