Patient information sheet

Principal investigator:

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Place of the Study:

Department of Gastroenterology and Human Nutrition

All India Institute of Medical Sciences, Ansari Nagar, New Delhi

Title of the Study:

"A Study to Evaluate Efficacy and Tolerability of Partial Enteral Nutrition with Exclusion Diet and its effect on microbiome change in Patients with Mild to Moderate Ulcerative Colitis: A Quasi-experimental study"

Purpose of the research

Ulcerative colitis is becoming a common disease in India. The disease occurs in the large intestine of patients and the common symptoms of this disease are diarrhea and bleeding per rectum. The disease is treated by variety of oral or intravenous medications depending upon the disease severity. The currently available agents are costly and not all patients respond to them. So, there is a need to develop efficacious and cost-effective therapies for this disease. The reason we are doing this research is to find out if the therapy we are testing (partial enteral nutrition) and dietary modifications can bring improvement in patients with mild to moderate ulcerative colitis. Studies have been done in similar disease known as Crohn's disease have found benefit with partial enteral nutrition and diet modifications. Partial enteral nutrition (PEN) is powdered formula which contains nutrients like protein, fats, carbohydrates, minerals and vitamins. Half of your daily calorie requirement is given in the form of PEN and you will be advised to avoid certain food products. The concept behind this treatment is that restoration of healthy gut microbiota will decrease disease symptoms.

Type of Research Intervention

The research will involve blood sample collection, fecal sample collection, and questionnaire that need to be filled during each visit

Participant selection

All adult patients (18 – 65 years of age) with ulcerative colitis who have active disease (mild to moderate) will be eligible for inclusion in the study.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Information on the trial drug

The therapies we are testing in this research are partial enteral nutrition (PEN) and exclusion diet. Partial enteral nutrition (PEN) is soya based powdered formula which contains nutrients like protein, fats carbohydrates, minerals and vitamins. Half of your daily calorie requirement is given in the form of PEN and you will be advised to avoid certain food products.

Unfamiliar Procedures

Because we do not know if the PEN is efficacious in patients with UC, we need to compare PEN in combination with exclusion diet with a standard treatment.

Participants in one group will be given the 50% calorie requirement will be provided in the form of PEN, along with diet modifications and the second group will be given standard treatment for ulcerative colitis. You will receive the treatment of your condition according to standard guidelines.

If we find that the treatment that is being used does not have the desired effect, or you have deterioration in your symptoms, we will use what is called a “rescue medicine.” The medicine that we will use is called steroid which will control your symptoms.

Description of the Process

During the research you will be followed up every 2 weeks till 4 weeks.

- In the first visit following procedures will be done,
    - You will undergo a detailed clinical assessment

- A small amount of blood, equal to about 2 teaspoons, will be taken from your arm with a syringe. The blood test will be done as a standard care and left-over sample will be disposed.
- You will give your stool sample in 1 containers and left-over sample will be disposed.
- If you are assigned to PEN + diet arm, you will receive powdered formula which you have drink by mixing with water at regular intervals till 4 weeks as directed and along with that you will be told to avoid certain food products which you have to avoid for 4 weeks.
- If you are in the standard treatment arm, then you will be given standard treatment with recommended drugs
- You will be asked to download IBD Nutricare mobile application in which you have to enter details of daily food intake

- At 2 and 4 weeks following procedures will be done
  - You will give your fecal sample in 1 container left over sample will be disposed after analysis at 4 weeks
  - You will have to fill certain questionnaires at 2 and 4 weeks

Duration

The research takes place over 4 weeks in total. During that time, it will be necessary for you to come to the hospital at 2 and 4 weeks. If you are not able to come you will be followed on phone.

Side Effects

There are no major side-effects associated with PEN. Some patients may develop bloating, nausea and increased frequency of stools following PEN.

You may not respond to any of these treatments and your disease may get worse. In such a case you will be withdrawn from the study and your treatment will be upgraded according to standard guidelines.

Risks

The are no risks during clinical assessment, blood or stool sample collection. You may only have slight pain during sample collection.

Benefits

By participating in this research, you may benefit from PEN and your disease may improve. If proven to be effective then PEN may be useful as an effective and safe alternative for all patients with mild to moderate ulcerative colitis.

Reimbursements

All your investigations as part of research will be done free of cost. You will not be given any money to participate in the study.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

Sharing the Results

The knowledge that we get from doing this research will be shared with you before it is made widely available to the public. Confidential information will not be shared. After this, we will publish the results in order that other interested people may learn from our research

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the IBD clinic, AIIMS.

Whom to Contact?

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact me on the contact details given on the first page.

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