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/Project:

"The effect of microbiome manipulation through diet and FMT in inducing and maintaining remission in patients with mild to moderate ulcerative colitis"

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 (fecal microbiota transplantation) and dietary modifications can bring improvement in patients with mild to moderate ulcerative colitis. Studies have been done in other countries which have found some use of faecal microbial transplantation in Ulcerative colitis. Faecal microbial transplantation is rectal instillation of faeces from a healthy donor to a diseased person. 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 colonoscopy (during a colonoscopy a thin flexible tube called a colonoscope is passed into the rectum (the back passage) and guided around the large bowel)

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 fecal microbiota transplantation (FMT) and UC specific diet. Fecal microbiota transplantation involves the infusion of fecal suspension (prepared through a standard technique) from a healthy donor in the patient through colonoscopy or rectal enema. FMT has been tested before in patients with ulcerative colitis, but studies have included small number of patients and some studies have shown it to be efficacious while some have not. The success depends both upon the type of donor and the disease activity of the patient. We are planning to take feces from healthy rural donors as we have shown recently that rural donors have the best quality of feces for FMT. The donors will be unrelated to you and the identity of the donors will not be revealed. FMT will be prepared in our labs using described techniques.

Unfamiliar Procedures

Because we do not know if the FMT is efficacious in patients with UC we need to compare FMT in combination with specific diet with a standard treatment. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the FMT and the second group will be given standard treatment for ulcerative colitis (5-aminosalicylic acid compounds). 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 8 weeks and subsequently at 12, 24, 36 and 48 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 4 containers and left over sample will be disposed.
    - You will undergo colonoscopy and first dose of the study medicine as per randomization will be administered as infusion through colonoscopy by one of the investigators.

    - If you are assigned to FMT + diet arm, you will receive 6 more colonoscopic infusions at 1,2,3,4,5 and 6 weeks and along with that you will be told to avoid certain food products.
    - If you are in the standard treatment arm, then you will be given standard treatment with recommended drugs
- At 8, 12, 24, 36 and 48 weeks following additional procedures will be done
    - You will give your fecal sample in 2 containers left over sample will be disposed after analysis at 8, 24 and 48 weeks
    - You will undergo colonoscopy at 8, 24 and 48 weeks

Duration

The research takes place over 48 weeks in total. During that time, it will be necessary for you to come to the clinic every 2 weeks till 8 weeks. Subsequently you have to come at 12, 24, 36 and 48 weeks.

Side Effects

There are no major side-effects associated with FMT. You may have discomfort during colonoscopic infusion and during self-administration of enemas. Some patients may develop fever after FMT which usually resolves within a day or 2.

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.

You may havepain during colonoscopy and there is 2-8/10000 (0.02 – 0.08%) risk of hole/ tear in your intestine during colonoscopy for which you may require urgent surgery.

Benefits

By participating in this research you may benefit from FMT and your disease may improve. If proven to be effective then FMT may be useful as a cheap, 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.

Who 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.