



Patient's sticker

Version 09/16

Consent Form For

Fecal microbial transplantation

Fecal transplant is an operation in which liquid produced from a healthy human being (as per a survey questionnaire and blood and feces tests) is introduced into the upper or lower gastrointestinal tract. The operation takes place using gastrointestinal endoscopy, enemas, nasogastric tube or a capsule.

The goals of the treatment: Transferring population of microorganisms (bacteria, viruses, fungi, etc.) from a healthy individual in order to improve the health of the person undergoing the operation, specifically, this treatment is currently approved for the treatment of persistent infection of clostridium difficile that did not respond to repeated antibiotic treatment.

in the case of fecal transplant through **the upper digestive tract**, the operation is performed using gastroscopy, in which a flexible instrument (gastroscope) is inserted into through the mouth into the stomach and into the duodenum and small intestine, and the liquid stools is flashed into there.

In the case of fecal transplant through **the lower digestive tract**, the operation is carried out through colonoscopy, in which a flexible instrument (colonoscopy) is inserted through the anus into the terminal small intestine or the colon's tip, where the liquid stools is flashed. The duration of the test is between 15-60 minutes.

These operations are performed under intravenous sedation and if performed using colonoscopy preparation is needed using laxatives guidelines as per the directions I received.

If treated with capsules, I will get 15 capsules per to swallow for two consecutive days (a total of 30 capsules).

If treated with an enema - the liquid stools shall be inserted through the rectum using an enema.

If treated with a nasogastric tube - the liquid shall be flashed through a nasogastric tube, after verifying that the nasogastric tube is located beyond filoros (the passage from the stomach into the duodenum) or by slow flashing of about two hours into the stomach.



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I acknowledge that the liquid stools flashed into my digestive system came from a donor tested for: Liver enzyme disorders, various pollutants such as HIV, hepatitis B, hepatitis C, Giardia and other intestinal infections or parasites. The donor confirmed to not engage in high-risk sexual habits, illegal drug abuse, tattoos or piercings within a period of 6 months prior to the donation. Donors were disqualified after reporting that they were treated with chemotherapy, suffer from an infectious disease, inflammatory bowel diseases, colon cancer, metabolic syndrome (obesity, high BP, and/or diabetes) or treated with antibiotics within the three months prior to the fecal donation.

Patient Name:

Last Name	First name	ID.	Father's Name
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I hereby declare and confirm that I received a detailed oral explanation from Dr.:

Last Name	First name
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of the need to perform fecal bacteria transplantation.

Diagnostic and treatment alternatives

Fecal transplant treatment is effective in 85-95% of the cases of infection with the clostridium difficile colitis, after a single treatment. Its effect is noticeable within a few days. If the transplant is ineffective it is possible to repeat it using liquid stools from another donor. There is a 5-15% chance that the treatment (implant) will not eliminate the clostridium difficile colitis, which will continue existing, or require antibiotic treatment.

I have been informed about the existence of treatment alternatives, their advantage, disadvantage, their side effects and their possible complications.

Testing limitations





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I was informed that despite the fact that this refers to an endoscopic examination that could detect polyps/tumors or other lesions, the purpose of the examination is fecal transplantation, and a diagnostic or treatment examination, if required, will be conducted at a later date, as per the decision of the treating physician.

Side effects and complications

I hereby declare and confirm that I received an explanation concerning the side effects of the primary treatment, including pain, discomfort and a sensation of swelling in the stomach or intestinal perforation which may occur as part of the endoscopic operation or fecal transplant.

Although the treatment is considered safe and reports of adverse events are rare, I was informed that this is an innovative treatment for which data is limited. It also received an explanation concerning the possible risks and complications, including the fact that the transfer of liquid stools from one person to another may involve the transfer of infections which we are not currently aware of, exposure to metabolic diseases such as diabetes or obesity, exposure to immune diseases such

as inflammatory bowel disease or exposure to the irritable bowel syndrome.

Also, the operation may lead to fever, systemic infection and even aspiration (inhaling) of liquid stools and severe pneumonia (in the case of fecal transplant from the upper digestive tract).

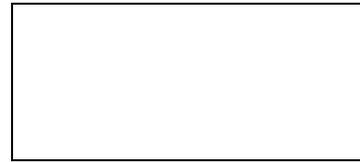
Other complications, specify:

If the treatment is done under sedation, my consent is hereby given for intravenous injection of sedatives, after I have been informed of the risks and complications of the sedative injection, including an allergic reaction of a varying degree to the anesthesia, and of the possible complications of using tranquilizers which might, rarely, cause respiratory disturbances and heart arrhythmias, mainly in patients with heart disease and in patients with respiratory disorders.

I acknowledge that if the medical center has a university branch, student may take part in the evaluation and treatment procedures, under full supervision.

I declare that I was given the possibility to ask questions and that all my questions were answered.

I acknowledge and agree that the primary treatment and all primary procedures shall be performed by whoever is assigned to perform them, in accordance with the procedures and regulations of the



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medical center, and that I was not promised that they shall be performed, neither in whole nor in part, by a certain specific person, provided they are performed with the acceptable responsibility and subject to the law.

I give my consent to perform fecal bacterial transplantation.



Date

Time

Patient Signature



Guardian's name (relatedness to the patient)

Guardian's signature (in the case of an incompetent minor or mentally ill)



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I confirm that I orally explained to the **patient/guardian/patient's translator** all the above in the required detailing, and that he/she signed a consent before me after I was convinced that he/she fully understood my explanations.



Physician's name (stamp)

Physician's signature

Date and time



Translator's name

His relatedness to the patient