

#	NCT Number	Study Title	Study URL	Study Status	Brief Summary	Study Results	Conditions
1	NCT04577729	The IRMI-FMT Trial	https://clinicaltrials.gov/study/NCT04577729	TERMINATED	Aim of the study is to investigate the effect of Fecal Microbiota Transplantation (FMT) and Checkpoint Inhibitor (CI) re-challenge in prior CI refractory patients on Progression free survival (PFS) and tumor using donor stool of former malignant melanoma patients, who have been in remission due to CI treatment for at least 1 year.	NO	Fecal Microbiota Transplantation Malignant Melanoma Stage III Malignant Melanoma Stage IV
2	NCT03353402	Fecal Microbiota Transplantation (FMT) in Metastatic Melanoma Patients Who Failed Immunotherapy	https://clinicaltrials.gov/study/NCT03353402	UNKNOWN	Altering the Gut Microbiota of Melanoma Patients Who Failed Immunotherapy Using Fecal Microbiota Transplantation (FMT) From Responding Patients. FMT includes both colonoscopy and stool capsules.	NO	Melanoma Stage Iv Unresectable Stage III Melanoma
3	NCT05251389	FMT to Convert Response to Immunotherapy	https://clinicaltrials.gov/study/NCT05251389	RECRUITING	In this study the aim is to investigate whether transfer of the microbiota of either responder or non-responder patients via fecal microbiota transplantation (FMT) can convert the response to immunotherapy in immune checkpoint inhibitors (ICI) refractory metastatic melanoma patients. This is a randomized double-blind intervention phase Ib/IIa trial in ICI refractory metastatic melanoma patients receiving either FMT of an ICI responding or FMT from an ICI non-responding donor, in combination with ICI. Following randomization, patients will receive vancomycin 250 mg, four times daily for 4 days (day -5 up until day -2), and undergo bowel clearance on day -1 (in total 1L MoviPrep). The FMT, either derived from donor group R (who showed a good response on anti-PD-1 therapy) or donor group NR (who showed progression on anti-PD-1 therapy), will be performed by a gastroenterologist using esophagogastroduodenoscopy. A total amount of 198mL (containing a total of 60 gram feces) will be used for transplantation. Anti-PD-1 treatment will be continued according to the patient's regular treatment schedule. Evaluation of safety and response to treatment will be performed.	NO	Melanoma Stage III Melanoma Stage IV
4	NCT04988841	Assessing the Tolerance and Clinical Benefit of fecal Transplantation in patientS With melanoma	https://clinicaltrials.gov/study/NCT04988841	RECRUITING	Recent studies suggest that patients with metastatic melanoma whose gut microbiome is colonized by eubiotic bacteria have a stronger anti-cancer response to anti CTLA-4 and anti PD1. The hypothesis of this research is that a pooled standardized fecal microbiome transfer (FMT) will shift melanoma patients' gut microbiome towards a	NO	Melanoma

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5	NCT04056026	A Single Dose FMT Infusion as an Adjunct to Keytruda for Metastatic Mesothelioma	https://clinicaltrials.gov/study/NCT04056026	COMPLETED	The investigators propose to ensure a favorable gut microbiome by fecal microbiota transplant to enhance the efficacy Keytruda	NO	Mesothelioma
6	NCT04056026	A Single Dose FMT Infusion as an Adjunct to Keytruda for Metastatic Mesothelioma	https://clinicaltrials.gov/study/NCT04056026	COMPLETED	The investigators propose to ensure a favorable gut microbiome by fecal microbiota transplant to enhance the efficacy Keytruda	NO	Mesothelioma
7	NCT04577729	The IRMI-FMT Trial	https://clinicaltrials.gov/study/NCT04577729	TERMINATED	Aim of the study is to investigate the effect of Fecal Microbiota Transplantation (FMT) and Checkpoint Inhibitor (CI) re-challenge in prior CI refractory patients on Progression free survival (PFS) and tumor using donor stool of former malignant melanoma patients, who have been in remission due to CI treatment for at least 1 year.	NO	Fecal Microbiota Transplantation Malignant Melanoma Stage III Malignant Melanoma Stage IV
8	NCT03353402	Fecal Microbiota Transplantation (FMT) in Metastatic Melanoma Patients Who Failed Immunotherapy	https://clinicaltrials.gov/study/NCT03353402	UNKNOWN	Altering the Gut Microbiota of Melanoma Patients Who Failed Immunotherapy Using Fecal Microbiota Transplantation (FMT) From Responding Patients. FMT includes both colonoscopy and stool capsules.	NO	Melanoma Stage Iv Unresectable Stage III Melanoma
9	NCT05251389	FMT to Convert Response to Immunotherapy	https://clinicaltrials.gov/study/NCT05251389	RECRUITING	In this study the aim is to investigate whether transfer of the microbiota of either responder or non-responder patients via fecal microbiota transplantation (FMT) can convert the response to immunotherapy in immune checkpoint inhibitors (ICI) refractory metastatic	NO	Melanoma Stage III Melanoma Stage IV

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					<p>melanoma patients. This is a randomized double-blind intervention phase Ib/IIa trial in ICI refractory metastatic melanoma patients receiving either FMT of an ICI responding or FMT from an ICI non-responding donor, in combination with ICI. Following randomization, patients will receive vancomycin 250 mg, four times daily for 4 days (day -5 up until day -2), and undergo bowel clearance on day -1 (in total 1L Moviprep). The FMT, either derived from donor group R (who showed a good response on anti-PD-1 therapy) or donor group NR (who showed progression on anti-PD-1 therapy), will be performed by a gastroenterologist using esophagogastroduodenoscopy. A total amount of 198mL (containing a total of 60 gram feces) will be used for transplantation. Anti-PD-1 treatment will be continued according to the patient's regular treatment schedule. Evaluation of safety and response to treatment will be performed.</p>		
10	NCT04988841	Assessing the Tolerance and Clinical Benefit of fecal tranSplantation in patientS With melanOma	https://clinicaltrials.gov/study/NCT04988841	RECRUITING	<p>Recent studies suggest that patients with metastatic melanoma whose gut microbiome is colonized by eubiotic bacteria have a stronger anti-cancer response to anti CTLA-4 and anti PD1. The hypothesis of this research is that a pooled standardized fecal microbiome transfer (FMT) will shift melanoma patients' gut microbiome towards a composition close to that associated with a better response, and will therefore increase the response to a combination of anti CTLA-4 and anti PD1, without affecting the safety of these drugs. The present trial is the first randomized trial of FMT in patients with unresectable or metastatic melanoma. It will include patients who have neither been exposed to anti CTLA-4 nor anti PD1 or PDL-1, prior to inclusion in the study. The pooled standardized fecal microbiome transfer administered in this study is an experimental drug MaaT013, a microbiome restoration biotherapeutic, produced by MaaT Pharma, and composed of pooled-donor, full-ecosystem intestinal microbiome. The MaaT013 product has a standardized richness (in number of species present) higher than a product obtained from a mono donor</p>	NO	Melanoma

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11	NCT03812705	Fecal Microbiota Transplantation for Steroid Resistant/Dependent Acute GI GVHD	https://clinicaltrials.gov/study/NCT03812705	COMPLETED	<p>(455 species approximately against 274 on average) and contains bacteria species (mentioned in the rationale) associated with better response to anti- CTLA-4 and anti PD1.</p> <p>The purpose of this study is to evaluate the efficacy and safety of fecal microbiome transplantation in patients with steroid resistant/dependent acute gastrointestinal graft-versus-host disease (GVHD). The patient will cease antibiotics treatment 1 day before FMT, and stop taking food 6 hours before FMT. Patients will be given Ondansetron intravenously 1 hour before FMT. Patients will be injected 200~300 ml fecal microbiome fluid to left colon by Colonoscopy or duodenum through duodenal tube by gastroscopy. If patient's condition is stable or improved within 1 week, second FMT may be performed 1 week later, up to 4 times will be performed if patient response. If patient's condition is not improved after the second FMT, ceasing FMT.</p> <p>The purpose of this study is to test the safety of FMT in patients with C. difficile and cancer. In previous other studies, FMT has been shown to cure C. difficile when antibiotics have failed, but most of these studies have not included patients with cancer. The investigators want to prove that FMT is safe in this group of people so that doctors will feel more comfortable prescribing it for their patients with cancer.</p>	NO	Hematopoietic and Lymphoid Cell Neoplasm
12	NCT02770326	Safety of Stool Transplant for Patients With Difficult to Treat C. Difficile Infection	https://clinicaltrials.gov/study/NCT02770326	COMPLETED	<p>The investigators propose to ensure a favorable gut microbiome by fecal microbiota transplant to enhance the efficacy Keytruda</p>	NO	C. Difficile Infection Cancer
13	NCT04056026	A Single Dose FMT Infusion as an Adjunct to Keytruda for Metastatic Mesothelioma	https://clinicaltrials.gov/study/NCT04056026	COMPLETED	<p>The investigators propose to use autologous fecal microbiota transplantation (AFMT) to acute myeloid leukemia (AML) patients treated with intensive chemotherapy and antibiotics in order to restore the balance of their intestinal microbiome and thereby eradicate treatment-induced multidrug resistant bacteria (MDRB), infection-related complications, as well as sequelae to the gastrointestinal tract. Therefore, the investigators propose to perform a single-arm multicentre prospective fecal microbiota transplantation (FMT) trial in AML patients receiving</p>	NO	Mesothelioma
14	NCT02928523	PreventiOn of DYsBioSis Complications With Autologous FMT in AML Patients	https://clinicaltrials.gov/study/NCT02928523	COMPLETED	<p>The investigators propose to use autologous fecal microbiota transplantation (AFMT) to acute myeloid leukemia (AML) patients treated with intensive chemotherapy and antibiotics in order to restore the balance of their intestinal microbiome and thereby eradicate treatment-induced multidrug resistant bacteria (MDRB), infection-related complications, as well as sequelae to the gastrointestinal tract. Therefore, the investigators propose to perform a single-arm multicentre prospective fecal microbiota transplantation (FMT) trial in AML patients receiving</p>	NO	Leukemia, Myeloid, Acute

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15	NCT03678493	A Study of FMT in Patients With AML Allo HSCT in Recipients	https://clinicaltrials.gov/study/NCT03678493	COMPLETED	<p>intensive chemotherapy, and who are usually heavily treated with broad-spectrum antibiotics during aplasia that generate a profound status of dysbiosis. For this purpose, at the time of admission and AML diagnosis, patients will be requested to donate stools that will be comprehensively screened, and if deemed appropriate according to protocol criteria, conditioned and stored frozen until future processing and transplantation after aplasia completion.</p> <p>This is a randomized, double-blind, placebo-controlled clinical trial of Fecal Microbiota Transplant (FMT) in 2 independent cohorts (60 acute myeloid leukemia patients undergoing intensive chemotherapy and 60 Allo-HCT patients). Participants in each cohort will be randomized in a 2:1 ratio to receive up to 3 treatments of FMT vs. placebo after each exposure to antibacterial antibiotics until 3 months after randomization.</p> <p>Tyrosine kinase inhibitors (TKIs) have improved the survival of patients with metastatic renal cell carcinoma, and are commonly used as first-line option for this condition, but their use is encumbered by side effects, mainly diarrhea, for which there are no standardized strategies. Increasing evidence suggests that gut microbiota could influence the development of TKIs-induced diarrhea. In theory, the therapeutic modulation of gut microbiota could be an approach to alleviate TKI-induced diarrhea. Fecal microbiota transplantation (FMT) is the infusion of fecal microbiota from a healthy donor in the gut of a recipient with the aim of curing a specific disease. It has been increasingly recognized as a highly effective treatment against recurrent <i>Clostridium difficile</i> infection. To date, the effects of FMT on chemotherapy-related diarrhea are unknown. This study will evaluate, through a randomized controlled design, the efficacy of fecal microbiota transplantation (FMT), compared with sham FMT, in treating TKI-induced diarrhea in patients with metastatic renal cell carcinoma.</p>	YES	Acute Myeloid Leukemia Allogeneic Hematopoietic Cell Transplantation
16	NCT04040712	Fecal Microbiota Transplantation in Tyrosine-kinase Inhibitors	https://clinicaltrials.gov/study/NCT04040712	COMPLETED	<p>Fecal microbiota transplantation (FMT) is the infusion of fecal microbiota from a healthy donor in the gut of a recipient with the aim of curing a specific disease. It has been increasingly recognized as a highly effective treatment against recurrent <i>Clostridium difficile</i> infection. To date, the effects of FMT on chemotherapy-related diarrhea are unknown. This study will evaluate, through a randomized controlled design, the efficacy of fecal microbiota transplantation (FMT), compared with sham FMT, in treating TKI-induced diarrhea in patients with metastatic renal cell carcinoma.</p>	NO	Diarrhea Caused by Drug (Disorder) Renal Cell Cancer
17	NCT03507140	Microbiota Study in Liver Transplanted Patients	https://clinicaltrials.gov/study/NCT03507140	COMPLETED	<p>Many studies describe the relationship between microbiota alteration and the occurrence of metabolic, alcoholic or inflammatory</p>	NO	Cirrhosis Hepatocellular Carcinoma Liver Transplant Microbiota

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					<p>liver diseases. Nevertheless, the modifications of microbiota during liver transplantation (LT) as well as its implication are poorly studied. Similarly, only the intestinal microbiota is studied in this context, and no data are available on the biliary microbiota, even if it is known that bile microbiota can interfere with hepatobiliary diseases. This study proposes a clinical and biological in-depth follow-up with multiple sampling of liver transplanted patients to study biliary and intestinal microbiota alterations along LT, as well as bile acids metabolism in corresponding fluids. Indeed, in recipient samples as saliva, blood, urine, and feces can be taken before LT, and surgeons can easily perform bile sampling during LT. In donors all samples can be taken during liver removal. This offers the opportunity to have a microbiotic landscape of individuals without liver disease (donor), and patients suffering from a chronic liver disease or a liver cancer before and after transplantation. Also, in Grenoble University hospital, in case of biliary anastomotic incongruence, a biliary stent is placed during LT in 60% of recipients. This stent is removed by endoscopic retrograde cholangiopancreatography (ERCP) within 6 months after LT, offering a second opportunity to obtain bile samples in transplanted patients, after the early post-LT period. Patients who do not require a biliary stent will also be included for the study of secondary objectives, as intestinal microbiota is very poorly characterized in liver transplanted patients too. A portion of the patients without biliary stent, may also develop an anastomotic biliary stricture requiring an ERCP. If this ERCP is realized within the follow-up period of the study, the patient will also be included in the primary objective of the study. These multiple and sequential samples will allow a complete analysis of microbiota changes in LT patients and aim to answer to 3 questions: 1. What are the modifications of intestinal and biliary microbiomes during LT? 2. What is the influence of bile acids' composition on intestinal and biliary microbiota? 3. What are the relationships between</p>		

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