A Multicenter Randomized Controlled Trial comparing the Efficacy of Transanal Irrigation versus Standard Bowel Care in patients with Parkinson Disease and severe constipation. Impact on Gut Microbiome and Motor Disorders. TAI-PD Study.

Organization's Unique Protocol ID 187/2025/Disp/AOUFe

Version 1 March 10th 2025

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

TAIPD Study

Patient Enrollment Number: _____
(to be completed by the Investigator)

Study Title:
Multicenter Randomized Controlled Trial on the Effectiveness of Transanal Irrigation versus Standard Bowel Management in Patients with Parkinson's Disease and Severe Constipation: Impact on Gut Microbiota and Motor Symptoms

Study Code: TAIPD Study

If you are the **legal representative** of the person invited to participate in this study, you will be asked to read and sign this document on their behalf in order to authorize participation in the study.

Dear Participant,

The information contained in this document is detailed and intended to help you make an informed decision about participating in this study. Please agree to participate only after carefully reading this information sheet and after having had a full and thorough discussion with a member of the research team, who will provide you with all necessary explanations and sufficient time to ensure that you fully understand what participation involves.

A. INTRODUCTION

You are being invited to take part in a clinical research study.

Before deciding whether to participate, it is important that you understand why the study is being conducted, what it involves, its possible benefits and risks, and your rights as a participant.

Please read this document carefully and ask any questions you may have. You may discuss this study with your family, your general practitioner, or anyone you trust before making your decision.

Participation is entirely voluntary. If you decide not to participate, your medical care will not be affected in any way.

You may take time to decide and keep a copy of this document.

B. STUDY INFORMATION

Why am I being invited?

You are being invited because you have **Parkinson's disease** and suffer from **severe chronic constipation**, which may cause:

- abdominal pain and bloating
- difficult bowel movements

- fecal impaction
- reduced quality of life
- hospital admissions for bowel obstruction management

We want to evaluate whether improving bowel function may also improve gut microbiota balance and Parkinson-related symptoms.

What is the purpose of this study?

The purpose of this study is to compare Transanal Irrigation (TAI) versus Standard Bowel Care (SBC) to determine which treatment is more effective in:

- improving constipation
- improving bowel regularity
- reducing complications related to constipation
- improving quality of life
- assessing effects on gut microbiota
- evaluating possible effects on Parkinson's motor symptoms

How many centers and participants are involved?

This is a **multicenter study** involving 11 Italian hospitals.

A total number of eligible patients with Parkinson's disease and severe constipation will be enrolled.

Can participation in the study cause side effects?

The study involves either a targeted medical treatment for constipation or transanal irrigation. These treatments are not expected to involve any additional risks or adverse effects beyond those commonly associated with standard constipation management, such as the use of laxatives or enemas.

How is the study designed?

This is a **randomized clinical study**.

Randomization means that a computer will assign you by chance (like flipping a coin) to one of two groups:

Group A: Transanal Irrigation (TAI)

TAI is a low-pressure bowel irrigation procedure using the **Irrisedo Flow® Qufora device**.

It involves:

- insertion of a soft rectal catheter/cone
- instillation of approximately 400 mL of water
- bowel evacuation stimulated by water pressure

The procedure:

- is performed every other day
- lasts about 20 minutes
- can be done independently or with caregiver support
- includes training by specialized nursing staff

Group B: Standard Bowel Care (SBC)

This includes:

- dietary fiber (25 g/day, at least 50% soluble)
- hydration (minimum 1.5 liters/day)
- abdominal massage
- laxatives as prescribed
- rectal stimulation (suppositories or micro-enemas if needed)

Treatment will be personalized by the study doctor.

How is the study designed?

This is a **prospective, multicenter, randomized interventional study**. If you agree to participate, you will be randomly assigned (by computer-generated randomization) to one of two treatment groups: **transanal irrigation (TAI)** or **standard medical bowel management**.

Regardless of the group you are assigned to, you will be followed and monitored by the study doctors according to established **Good Clinical Practice (GCP)** standards and routine clinical protocols for the management of bowel dysfunction related to neurological diseases, including Parkinson's disease.

What will happen if I participate?

Your participation will last **24 months**.

Study visits include:

- Baseline visit
- Telephone follow-up at 1 month
- Visit at 6 months
- Telephone follow-up at 12 months
- Final visit at 24 months

At baseline, you will:

- undergo clinical evaluation
- answer questionnaires about constipation and Parkinson symptoms
- provide a stool sample for microbiota analysis
- complete a 2-week food diary

Additional stool samples may be collected during follow-up visits.

No additional invasive tests beyond standard clinical care are required.

RISKS AND DISCOMFORTS

Risks of Transanal Irrigation

Possible side effects include:

- rectal discomfort
- abdominal cramps
- rectal bleeding
- mucosal irritation
- nausea
- diarrhea
- temporary fecal incontinence

Rare complication:

- bowel perforation (very rare)

Risk is minimized through training and medical supervision.

Risks of Standard Bowel Care

Possible side effects include:

- bloating
- gas
- abdominal discomfort
- diarrhea
- dehydration
- electrolyte imbalance
- laxative dependency (with prolonged use)

Your treatment will be monitored to reduce these risks.

BENEFITS

You may benefit from:

- improved bowel evacuation
- reduced constipation
- reduced abdominal discomfort
- fewer fecal impactions
- reduced hospital admissions
- improved quality of life

However, benefits cannot be guaranteed.

The information collected may help improve future treatment for patients with Parkinson's disease.

ALTERNATIVES

You do not have to participate.

If you choose not to participate, you will continue receiving standard medical care and approved treatments.

WITHDRAWAL FROM THE STUDY

Your participation is voluntary.

You may withdraw at any time, without giving a reason.

Stopping participation will not affect your future care.

The investigator may also stop your participation if:

- participation becomes unsafe
- new information becomes available
- study procedures are not followed
- the study is stopped by regulatory authorities

CONFIDENTIALITY AND DATA PROTECTION

Your personal and medical data will be handled according to **EU GDPR Regulation (2016/679)**.

Your data will be:

- coded (pseudonymized)
- stored securely
- accessed only by authorized personnel

Your identity will never appear in scientific publications.

Regulatory authorities may review study data for verification.

BIOLOGICAL SAMPLES

Stool samples collected during the study will be:

- coded
- stored at -80°C
- analyzed for gut microbiota research

Samples will be destroyed after study completion unless you provide separate consent for further storage.

COSTS AND COMPENSATION

Participation in this study is free of charge.

No financial compensation will be provided.

The study device (Irrisedo Flow®, Qufora) is covered by the Italian National Health Service.

ETHICS APPROVAL

This study has been reviewed and approved by the appropriate Ethics Committee and will be conducted according to Good Clinical Practice (GCP) and the Declaration of Helsinki.

CONTACT INFORMATION

For questions or emergencies:

Dr. Simona Ascanelli
Email: simona.ascanelli@unife.it
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Emergency surgical unit (24h):
+39 0532 236364

INFORMED CONSENT

I confirm that:

☐ I have read and understood this information sheet.
☐ I have had the opportunity to ask questions and received satisfactory answers.
☐ I understand the purpose, procedures, risks, and benefits of the study.
☐ I understand that participation is voluntary.
☐ I understand that I can withdraw at any time without affecting my medical care.
☐ I agree to the collection and use of my medical data for this study.
☐ I agree to the collection and analysis of my stool samples for this study.
☐ I have received a copy of this consent form.

I voluntarily agree to participate in the TAIPD Study.

INDEPENDENT WITNESS

(To be completed if the patient/parent/legal representative is unable to read or sign)

I, the undersigned:_____

confirm that I was present during the information and consent discussion between Dr. _____ and Mr./Ms. _____, and I confirm that the latter was unable to provide written consent personally.

_____ ___/___/___

Full Name of Independent Witness Date Signature

DECLARATION OF THE MEDICAL DOCTOR OBTAINING CONSENT

_____

(Patient's full name, place and date of birth)

Study Title:_____

Protocol Code, Version and Date:_____

Study Sponsor:_____

Principal Investigator (Name, Affiliation, Contact Details):_____

I, the undersigned Prof./Dr. _____
Surname First Name

in my capacity as **Principal Investigator** (or delegated investigator),

hereby declare that:

the patient has voluntarily agreed to participate in this clinical study.

I further declare that I have:

☐ provided full and clear explanations regarding the purpose of the study, its procedures, possible risks and benefits, and available alternatives;

☐ verified that the participant has adequately understood the information provided;

☐ allowed sufficient time and opportunity for the participant to ask questions regarding the study;

☐ clearly explained the participant's right to withdraw from the study at any time or modify their decisions without consequences;

☐ not exercised any coercion or undue influence in obtaining this consent;

☐ provided information on how the results of the study will be communicated.

If applicable:
☐ provided the parents/legal guardian with a simplified information sheet intended for minors aged 7–11 years and explained the importance of informing the child, using methods and language appropriate to their age, about the study in which they may participate.

_____ ___/___/___

Place and Date Time

_____

Full Name of the Physician (printed) Signature (and stamp)

who provided the study information and obtained consent

This form is an integral part of the informed consent process and must be kept together with the Patient Information Sheet.

Participant's Full Name (printed) Legal Representative's Full Name (printed)

Date _____ **Date** _____

Signature _____ **Signature** _____

If a legal representative has been appointed, the study physician will verify that the guardianship order includes healthcare decision-making authority.

Study Physician's Full Name (printed)

Date _____

Signature _____

Participant Name: _____

Signature: _____

Date: _____

Investigator Name: _____

Signature: _____

Date: _____