Stomie 3D Protocol

- Interventional Research with Minimal Risks and Constraints -

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"Impact of preoperative placement of a 3D-printed stoma on the quality of life of ostomy patients"

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SIGNATURE PAGE

DEVELOPER'S SIGNATURE

The sponsor agrees to conduct this study in accordance with all applicable laws and regulations governing the research and in accordance with the protocol.		
Name and title of the signing representative: Mr. Francis SAINT-HUBERT General Director of CHD Vendée	**Date:**	**Signature:**

SIGNATURE OF THE INVESTIGATOR' S

I have read all pages of the clinical trial protocol sponsored by CHD Vendée. I confirm that it contains all the information necessary to conduct the trial. I agree to conduct the trial in accordance with the protocol and the terms and conditions set forth therein. I agree to conduct the trial in accordance with:

- the principles of the "Declaration of Helsinki,"
- the laws and regulations of the Public Health Code applicable to Category 2 Regional Public Health Institutes (RIPH) as well as the associated implementing regulations

I also undertake to ensure that the investigators and other qualified members of my team have access to this protocol as well as to the documents relating to the conduct of the trial to enable them to work in compliance with the provisions set forth in these documents.

Principal Investigator	**Name:** Dr. Emeric ABET	**Date:**	**Signature:**
Principal Investigator	**Name and institution:** Dr. Emeric ABET CHD Vendée	**Date:**	**Signature:**

LIST OF ABBREVIATIONS

ANSM	French National Agency for Medicines and Health Products Safety
ARC	Clinical Research Associate (monitor)
CPP	Committee for the Protection of Persons
CNIL	National Commission for Information Technology and Civil Liberties
CRF	Case Report Form
CSP	Public Health Code
eCRF	Electronic Case Report Form
ITT	Intention to Treat
MR	Reference Methodology (CNIL)
PP	Per Protocol
GDPR	General Data Protection Regulation
RIPH	Research Involving Human Subjects
RIRCM	Interventional Research with Minimal Risks and Constraints

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INTRODUCTION

The creation of a stoma in patients is experienced as a traumatic event. The stoma alters body image and self-esteem and leads to increased anxiety. These changes affect patients' quality of life(1) . To reduce the negative impact of the stoma, patients are seen in preoperative consultations by stoma care nurses. This consultation allows nurses to show patients what a stoma looks like (using a photograph), the equipment used, and how it works.

In 2016, McKenna et al.(2) demonstrated the benefits of marking (with a marker) the stoma site on the abdomen preoperatively. In this study, patients who received preoperative marking had a higher postoperative quality of life score than patients without marking ($p=0.03$).
Quality of life was assessed using the STOMA-QOL score(3) . This quality-of-life score is specific to ostomy patients. It evaluates four dimensions: sleep, intimate relationships, relationships with family and close friends, and relationships with people other than family and close friends. This questionnaire consists of 20 questions and has been validated in five languages, including French.

The objective of this pilot study is to evaluate the postoperative quality of life of ostomy patients who received preoperative therapeutic education involving the use of a 3D-printed stoma button in addition to marking the surgical site with a marker, compared to marking the surgical site with a marker alone, during the 15 days prior to surgery.

1. RATIONALE FOR THE STUDY

1.1. RESEARCH CONTEXT

Colorectal surgery is a complex procedure, particularly rectal surgery. Patients with rectal adenocarcinoma most often undergo neoadjuvant treatment with chemoradiotherapy. This treatment improves oncological outcomes but makes surgery more difficult.
To reduce the severity of anastomotic fistulas, it is recommended to perform a diversion stoma for infraperitoneal anastomoses (4). This diversion stoma can be performed either on the terminal small intestine (ileum): ileostomy, or on the colon: colostomy. In France, it is estimated that 80,000 patients have a stoma, with the following breakdown:

- 50,000 colostomies
- 20,000 ileostomies
- 10,000 urostomies.

There are an estimated 16,000 new ostomates each year in France.

Creating a stoma involves connecting a segment of the intestine to the skin. This procedure alters the patient's body image, as they no longer have bowel movements through natural channels but instead wear a stoma bag that must be emptied when full and requires care around the stoma.
Furthermore, these stomas cause significant anxiety (1) and discomfort (gas, stool leakage, and pouch detachment) in patients, with major repercussions on daily life (patients isolating themselves and no longer daring to leave their homes).

To improve patient care, it has been shown that a preoperative consultation with a stoma therapist helps patients better understand the stoma (5). During this consultation, the stoma therapist explains how the stoma works and demonstrates the equipment used. Patients also view photos showing the appearance and shape of the stoma.
During this consultation, the stoma therapist marks the site of the future stoma on the abdomen to identify the most appropriate location for positioning the stoma. This marking helps improve patient care and their postoperative quality of life (2).
The objective of our pilot study is to evaluate the postoperative quality of life of ostomy patients who underwent preoperative therapeutic education sessions involving marking the surgical site with a marker alone versus the use of a 3D-printed stoma button in addition to marking the surgical site with a marker.
We believe the use of a modeled device is beneficial for representing the stoma. The stoma is bordered by the skin and protrudes 1 to 2 cm above the skin surface. Consequently, a three-dimensional device provides a more accurate representation of the stoma than marker pen marking alone.
Currently, there are no studies in the literature reporting on this type of device in the care of ostomy patients.

The long-term goal is to improve patient education by providing preoperative training. This pre-education will help them better understand the stoma, which alters body image and has significant psychological implications.

1.2. BENEFITS AND RISKS FOR RESEARCH PARTICIPANTS

1.2.1. Benefits

1.2.1.1. Individual benefit

The expected benefit of using a 3D-printed stoma button in addition to marking the surgical site with a marker, compared to marker marking alone, is an improvement in the quality of life for ostomy patients through enhanced preoperative care. This care would help patients better understand the stoma and the associated equipment.
During this consultation, the stoma simulation device will be positioned on the patient's abdomen so that they can visualize the final placement of the stoma. The patient will keep this 3D print for the 15 days leading up to the procedure. By visualizing this "fake" stoma, the patient will be able to gradually accept their real stoma, thereby reducing anxiety related to it.

1.2.1.2. Collective Benefit

Implementing the device would allow patients to learn to manage their stoma more quickly by reducing apprehension and improving their handling of the equipment. This learning process will help shorten hospital stays, as patients must be able to manage their stoma independently in order to return home.

1.2.2. Risks

1.2.2.1. Individual risks

- Risks associated with 3D stoma creation
    - poor skin tolerance of the ostomy simulation device,
    - the possibility of detachment,
    - intolerance to the fixation system,
- Risks associated with marking the surgical site with a marker:
    - intolerance to the marker (ink/components) or to the marking protection system.

1.2.2.2. Collective risk

No risks are anticipated.

1.2.3. Benefit-risk balance

The principal investigator classifies this study as **a Minimal-Risk Interventional Study (MRIS)** as a first-line approach, since:

- ✓ All procedures are performed in the usual manner (intervention, etc.) and are defined in the decree of April 12, 2018, issued by the Ministry.

The research does not involve techniques or strategies that are either innovative or obsolete. The expected benefits are relatively significant with minimal risks.
Since the techniques and medications are used in routine practice, no increased risk is expected compared to these practices due to participation in the protocol.

The patient's entire care will be identical to standard practice. In particular, the discharge date will be decided by the physician in charge of the patient, independently of the study, but will be recorded in the patient's medical record and the research case report form (CRF).

Consequently, the specific implementation procedures of the research pose negligible constraints for the person participating in the study. (Article R 1121-3 of the Public Health Code, Decree No. 2006-477 of April 26, 2006)

The principal investigator shall therefore submit the study protocol to the Ile-de-France XI Committee for the Protection of Persons (CPP) Ile-de-France XI for a favorable opinion and confirmation of the study's eligibility, in accordance with Article L 1121-1 of the Public Health Code, as set forth in Laws No. 2004-806 of August 9, 2004, and No. 2006-450 of April 18, 2006, relating to public health policy.

2. OBJECTIVES AND EVALUATION CRITERIA

2.1. MAIN OBJECTIVE AND EVALUATION CRITERION

2.1.1. Primary objective

To evaluate the postoperative quality of life of ostomy patients who received preoperative therapeutic education involving the use of a 3D-printed stoma button combined with marking the surgical site with a marker versus marking the surgical site with a marker alone.

2.1.2. Primary Outcome Measure

Total score on the Stoma-QOL questionnaire (Appendix 2) 2 months after hospital discharge.

2.2. SECONDARY OBJECTIVES AND EVALUATION CRITERIA

2.2.1. Secondary objectives

To evaluate:

- Quality of life 1 month after hospital discharge
- Length of hospital stay

2.2.2. Secondary evaluation criteria

- Total score on the Stoma-QOL questionnaire (Appendix 2) 1 month after hospital discharge
- Assessment of length of hospital stay in days

3. STUDY POPULATION

3.1. DESCRIPTION OF THE STUDY POPULATION

This study focuses on patients scheduled to undergo their first ileostomy, with an indication for a temporary stoma.
The Vendée Departmental Hospital Center (CHD) treats 25 new patients per year.
The study plans to randomize 50 patients.
Patients participating in the “Stomie 3D” study will not be allowed to participate simultaneously in another interventional study (excluding interventional studies with minimal risks and constraints) for the entire duration of their participation in the study (i.e., 2 months).

3.2. INCLUSION CRITERIA

- Patient ≥ 18 years of age,
- First ileostomy with an indication for placement of a temporary stoma,
- Patient with scheduled surgery,
- Patient capable of understanding the protocol and having given consent to participate in the research,
- Patient with health insurance coverage.

3.3. EXCLUSION CRITERIA

- Patients under 18 years of age,
- Patients with an indication for permanent stoma creation,
- Patients undergoing emergency surgery,
- Pregnant or breastfeeding patients, or patients of childbearing age without effective contraception,
- Patients under guardianship, conservatorship, or legal protective measures,
- Patients participating in another interventional clinical research protocol involving a drug or medical device.

3.4. EXPECTED DURATION OF PARTICIPANT INVOLVEMENT AND DESCRIPTION OF THE TIMELINE AND DURATION OF ALL TRIAL PHASES, INCLUDING FOLLOW-UP, IF APPLICABLE

Enrollment period: 54 months

Follow-up duration: 2 months post-discharge from hospitalization + 15 days (corresponding to the duration of marking the surgical site with a marker / placing the 3D-printed stoma button in addition to marking the surgical site with a marker)

Total study duration: 56 months + 15 days

Upon the first enrollment, the sponsor must immediately notify the competent authority and the CPP of the effective start date of the study (effective start date = date of obtaining oral consent from the first participant).

The study end date will be reported by the sponsor to the French National Agency for Medicines and Health Products Safety (ANSM) and the CPP within 90 days. The study end date corresponds to the end of participation by the last person participating in the study.

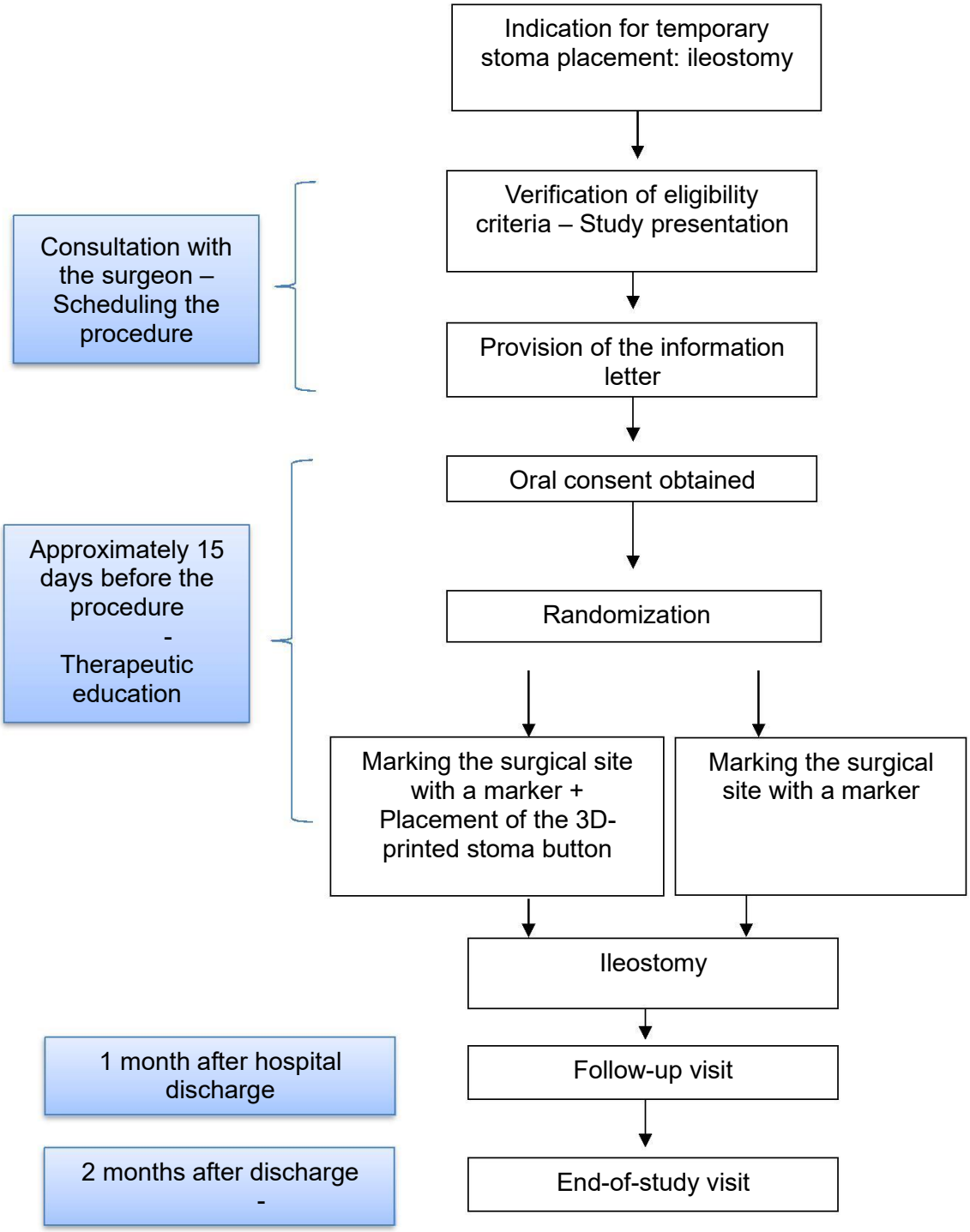
4. STUDY DESIGN AND PROCEDURE

4.1. GENERAL RESEARCH METHODOLOGY

The study has the following characteristics:

- Interventional Study with Minimal Risks and Constraints (RIRCM)
- Single-center
- Controlled
- Randomized, parallel-group
    - Control group: Surgical site marking with a marker pen only
    - Experimental group: Placement of a 3D-printed stoma button combined with marking the surgical site with a marker pen
- Open-label

4.2. STUDY DESIGN



4.3. STUDY TIMELINE

The patient is seen for a preoperative consultation during which the surgeon schedules a procedure to create a temporary stoma. At this time, the study will be explained to the patient, and an information letter will be provided.

The patient will then be seen by the stoma therapist approximately 15 days before the surgical procedure. During this therapeutic education session, the patient's verbal consent will be obtained, and randomization may be performed by the stoma therapist.

The randomization arm will allow for the marking of the future stoma site:

- Marking the surgical site with a marker only
- Marking the surgical site with a marker followed by placement of the 3D-printed stoma button

The quality of life questionnaire (Stoma-QOL, provided in Appendix 2) must be completed by the patient at the start of the consultation, 1 month, and 2 months after hospital discharge.
If the follow-up visits scheduled for 1 and 2 months after discharge do not coincide with scheduled appointments, these visits may be conducted via telephone.

STUDY TIMELINE

Actions	Consultation with the surgeon	**Inclusion visit** (*Consultation with the stoma therapist: 15 days ± 5 days before surgery)*	**Follow-up visit** *(Surgical consultation: 1 month after hospital discharge ± 1 week)*	**End-of-study visit** *(Surgical consultation: 2 months after hospital discharge ± 1 week)*
Verification of patient eligibility	X			
Patient information	X			
Verbal informed consent		X		
Randomization		X		
Medical history[1]		X		
Stoma-QOL Questionnaire[2]			X	X
Events of interest[3]		X*		
New Developments/Special Circumstances		X	X	X

[1] *Stroke, Hemiplegia, Obesity.*

[2] *To be completed by the patient at the start of the consultation.*

[3] *Events of interest to be recorded are:*

- *Regarding the 3D-printed stoma button: poor skin tolerance (local reaction, irritation, discomfort, pruritus), detachment, dislodgement, local intolerance to the fixation system (rash, pruritus, burning sensation, irritation),*

local intolerance to the protective system (rash, pruritus, burning sensation, irritation), poor adhesion of the protective system;

*Related to marking the surgical site with a marker pen: skin intolerance such as a local reaction to inks and solvents, intolerance (rash, pruritus, burning sensation, irritation), poor adhesion of the protective system, premature fading; * Adverse events must be recorded up to the time of ileostomy (i.e., for the entire duration of the 3D-printed stoma in place, in addition to surgical site marking with a marker pen or surgical site marking with a marker pen alone).*

4.4. DESCRIPTION AND RATIONALE FOR THE TREATMENT PROTOCOL

Patients attend a therapeutic education consultation with the stoma therapist approximately 15 days before surgery. During this consultation, the following is provided:

- an informational booklet on stomas and their appliances,
- a consent form,
- a diagram of the digestive system and the location of the stoma
- and a sample of a drainable pouch (1- or 2-piece) that is either transparent or opaque.

During this consultation, the stoma therapist asks the patient to perform various movements (standing up, sitting down, squatting, bending forward) to determine the best possible location for the future stoma. The reference point is located between the navel, the iliac crest, and the pubic bone. The patient will be positioned in front of a mirror so they can see the stoma site and perform their own care.

Patient in the “Marking the surgical site with a marker only” group:

Once the optimal surgical site has been selected, it will be marked with a marker pen and then covered with a clear dressing to protect the marking and prevent it from fading during washing. It is important that the marked site remains clearly visible so that the surgeon can use it to guide the placement of the future stoma.

Patient in the “Marking the surgical site with a marker combined with the placement of a 3D-printed stoma button” arm:

The surgical site will also be marked with a marker for patients in the experimental group so that the surgeon can use it during the surgical procedure. The 3D stoma button will then be placed on a Stomahésive® plate the size of the device and adhered to the patient’s skin at the site defined by the marker.

A transparent dressing will cover the entire area and ensure the device is watertight.

The 3D-printed stoma button will be removed upon entering the operating room.

4.5. DESCRIPTION OF THE EVALUATION AND DATA COLLECTED

The Stoma-QOL questionnaire (excerpt from the Coloplast Laboratories brochure – September 2007) is a quality-of-life questionnaire. This questionnaire was developed for ostomy patients (colostomy or ileostomy patients).
It is a short questionnaire (20 items) designed for self-assessment or peer assessment. It evaluates four domains:

- sleep,
- intimate relationships,
- relationships with family and close friends,
- relationships with people other than family and close friends.

This questionnaire has been validated in French. It can be either self-administered or completed during face-to-face or telephone interviews.
Scores can be used cross-sectionally to assess ostomy-related problems or longitudinally to track the patient's progress
It takes 5 to 10 minutes to complete the questionnaire.

4.6. IDENTIFICATION OF ALL SOURCE DATA NOT INCLUDED IN THE MEDICAL RECORD

- The Stoma-QOL score at 1 month and 2 months post-discharge
- The number of unscheduled visits made by the stoma therapist

4.7. RULES FOR DISCONTINUING A PERSON'S PARTICIPATION

4.7.1. Criteria for premature termination of a participant's involvement in the study

A participant's participation may be terminated prematurely for the following reasons:
- Withdrawal of consent by the patient,
Participants may withdraw their consent and request to leave the study at any time and for any reason.
- Death.

4.7.2. Follow-up procedures , and data collection schedule

For patients who have been excluded from the study (by choice, death, or other reasons), these patients will not continue with the study schedule.

In the event of the patient's withdrawal of consent, and without prejudice to the patient's rights, the data already collected will be analyzed in accordance with Article L1122-1-1 of the CSP.

No other tests specifically provided for in the protocol will be performed, and no data will be used in accordance with the patient's wishes after withdrawal of consent.

A patient's withdrawal from the study will not alter their usual care for their condition in any way.

4.7.3. Termination of part or all of the research upon the sponsor's decision (excluding biostatistical considerations)

Part or all of the study may be permanently or temporarily halted by decision of the ANSM, the CPP, or the study sponsor.

In all cases:

- Written confirmation will be sent to the study's principal investigator (specifying the reasons for early termination),
- All study patients will be informed.

5. SAFETY MONITORING

As this study constitutes a Category 2 RIPH (Research Involving Human Subjects), the applicable provisions regarding vigilance are those established for the practice of healthcare and the use of products associated with the study in accordance with Article L1123-10 of the Public Health Code.

6. DATA MANAGEMENT AND STATISTICS

6.1. COLLECTION AND PROCESSING OF STUDY DATA

6.1.1. Data Collection

An electronic case report form (eCRF) will be created for each patient. All information required by the protocol must be provided in the eCRF. It must include the data necessary to confirm compliance with the protocol and all data required for statistical analyses; it must enable the detection of major deviations from the protocol.

The individuals responsible for completing the eCRF (investigator, Clinical Research Associate (CRA), etc.) must be designated and will be identified in the task delegation table for each center (kept in the investigator's binder).

6.1.2. Data Coding

By signing this protocol, the principal investigator and all co-investigators agree to keep the identities of the patients who participated in the study confidential.

The transmission of an individual's data for research purposes will therefore only be possible subject to the application of a coding system; the presentation of research results must exclude any direct identification.

Patients will be identified based on the order of their inclusion using a number automatically assigned by the Clinsight software (eCRF), followed by the patient's initials (first letter of the first name + first letter of the last name).
This code will be the only information appearing in the case report form (eCRF) and will allow the eCRF to be linked to the patient retrospectively.
The investigator is also required to code patient data on all documents in their possession (imaging reports, laboratory test results, etc.) that are attached to the eCRF.

A cross-reference table will be established at the participating site. This table will be kept in a secure location by the site's principal investigator and will contain the patient code and their identifying information so that the patient record can be traced in the event of missing or erroneous data. No clinical data will be collected in these cross-reference tables.

6.1.3. Data Processing

The collection of clinical data will be based on the establishment of a database and the creation of data entry forms modeled after the observation log, in accordance with the protocol and current regulations.

Pursuant to Article L1122-1-2 of the Public Health Code and subject to the consent of the research participants, the data collected as part of this study may be used for future research on ostomy care. Such research may be conducted either solely by the teams at CHD Vendée or in collaboration with other public research teams in France. Each study conducted with a partner team will be subject to a contractual framework requiring that partner to comply with the obligations of the General Data Protection Regulation (GDPR).

6.2. STATISTICS

Head of Statistical Analysis:

Lucie Planche
Vendée Departmental Hospital
Clinical Research Unit
lucie.planche@chd-vendee.fr

Software
Analyses will be performed using R software version 3.5.1

6.2.1. Description of the planned statistical methods, including the schedule for planned interim analyses

All variables will be described overall and by group. The description will include frequencies and percentages of categories for qualitative variables and the minimum, maximum, mean, standard deviation, and median for quantitative variables.

Stoma-QOL Questionnaire

Patients' quality of life will be measured using the Stoma-QOL questionnaire at M1 and M2.
The total questionnaire score will be estimated in each group using a mixed-effects linear model that accounts for the repeated nature of the data. The group effect, the time effect, and the time-group interaction will be evaluated.

In the event of non-normality of the model residuals, a nonparametric test will be considered (Kruskal-Wallis test).

Length of hospital stay

Length of hospital stay will be compared using a Kruskal-Wallis test.

6.2.2. Statistical justification of the sample size

This is a pilot study. The objective of this study is to obtain reliable data on the quality of life of ostomized patients. These data will thus enable the design of a multicenter comparative study. According to the validation data for the Stoma-QOL questionnaire, the average quality of life score in France was estimated at 53.8 with a standard deviation of 10. With a sample size of 23 patients in each group, this study will, with 90% power and a 5% alpha level, be able to detect a 10-point difference between the groups. To ensure the study's power, a total of 50 patients will be randomized. As many patients as necessary will be included to reach the target of 50 randomized patients.

6.2.3. Expected level of statistical significance

The alpha level is set at 5%.

6.2.4. Statistical criteria for stopping the study

Not applicable

6.2.5. Method for handling missing, unused, or invalid data

All missing data and the reasons for them will be described in each group.

The primary endpoint will be analyzed using a linear mixed-effects model that accounts for the repeated nature of the data. This approach allows for the inclusion of individuals with missing data. Therefore, no imputation method will be applied.

For the analysis of secondary endpoints, no imputation will be performed

6.2.6. Management of changes made to the analysis plan of the initial strategy

Not applicable

6.2.7. Selection of subjects to be included in the analyses

The primary analysis will be conducted on the Intention-to-Treat (ITT) population, i.e., all randomized patients.

A supplementary analysis will be conducted on the Per Protocol (PP) population, including randomized patients for whom no major deviations from the protocol were identified.
A data review meeting will be organized to review and determine whether each deviation constitutes a major or non-major criterion.

6.2.8. Randomization

Randomization will not be stratified.

It will be conducted in a 1:1 ratio and performed in blocks.

Randomization will be performed using Ennov Clinical via the website: https://www.dirc-hugo-online.org/csonline/. Access will be granted using a username, password, and study number provided by the data manager of the CHD Vendée Research Unit. The following information must be entered:

- First initial of the first name,
- First initial of the first name,
- Month and year of birth,
- Compliance with inclusion and exclusion criteria (yes/no).

Randomization will be performed by the investigator or any authorized person after confirming the participant's eligibility for the study and obtaining their consent. The enrollment number will be assigned automatically during randomization. A confirmation email will be sent to the person who performed the randomization as well as to all relevant parties.

The randomization list will be prepared by the statistician at the CHD Vendée Research Unit. An explanatory guide to randomization will be available online via Ennov Clinical.

7. ADMINISTRATIVE AND REGULATORY ASPECTS

7.1. RIGHT OF ACCESS TO DATA AND SOURCE DOCUMENTS

Investigators will make available to those responsible for monitoring, quality control, or auditing the research, the documents and individual data strictly necessary for such oversight, in accordance with applicable laws and regulations (Articles L.1121-3 and R.5121-13 of the Public Health Code).

Source documents, defined as any original document or item that proves the existence or accuracy of data or facts recorded during the clinical trial, will be retained for 15 years by the investigator or by the hospital if the document is part of a hospital medical record.

7.2. DATA CONFIDENTIALITY

Individuals with direct access shall take all necessary precautions to ensure the confidentiality of information relating to the participants, particularly regarding their identity and the results obtained.
These individuals, like the investigators themselves, are bound by professional confidentiality (in accordance with the conditions defined by Articles 226-13 and 226-14 of the Penal Code).
During the study or upon its completion, the data collected on the participants and transmitted by the researchers will be pseudonymized.
Under no circumstances may the names or addresses of the individuals concerned be disclosed in plain text.
Only the first letter of the subject's first and last name, along with their month and year of birth, will be recorded, accompanied by a study-specific coded number indicating the order of subject inclusion.

7.3. TRIAL MONITORING

Monitoring will be carried out by the Promotion Unit of the Clinical Research Unit at CHD Vendée. A Clinical Research Coordinator (CRC) will visit the site regularly to perform quality control on the data reported in the observation logs.

The monitoring plan is defined in consultation between the research team and the responsible institution based on the study's objectives.

The protocol has been classified according to the estimated level of risk to the patient participating in the study. It will be monitored as follows:

Risk B: foreseeable risk similar to that of standard care

On-site monitoring visits will be scheduled after consultation with the investigator. Clinical Research Coordinators (CRCs) must be able to access the following at each site:

- the data collection forms for enrolled patients,
- the patients' medical and nursing records,
- the investigator's binder.

7.4. INSPECTION / AUDIT

As part of this study, an inspection or audit may take place. The sponsor and/or participating centers must be able to provide access to the data to the inspectors or auditors.

7.5. NOTIFICATION TO THE COMPETENT AUTHORITIES

The sponsor undertakes to submit the study protocol for prior approval by an Institutional Review Board (IRB). The information provided covers, on the one hand, the methods and nature of the research and, on the other hand, the safeguards provided for patients participating in this trial.

This protocol will also be submitted to the ANSM for review.

7.6. AMENDMENTS TO THE PROTOCOL

Requests for substantial amendments will be submitted by the sponsor to the relevant CPP for review in accordance with applicable law and its implementing regulations.

The amended protocol must be provided in a dated, updated version.

The patient information and consent form must be amended if necessary.

7.7. ELECTRONIC DATA AND SUBMISSION TO THE CNIL

The data collected as part of this study are collected for scientific research purposes, in the public interest.

This study falls under the “Reference Methodology” MR-001, registered for the CHD Vendée under No. 2060482 v 0, for the following reasons:
- Collection of health data for research purposes
- Obtaining approval from an Ethics Committee to begin the research
- Use of pseudonymized data
- Individual notification of the persons concerned
- Access to data limited to professionals (healthcare and sponsor personnel) involved in the study.

The fact that this study falls under MR001, along with the reasons, will be recorded in the sponsor’s data processing register.

7.8. PATIENT INFORMATION

The investigator undertakes to obtain the person’s free, informed, and express consent, collected orally, after providing them with information on the protocol (information letter and oral consent form). The investigator will provide the person with a copy of the information letter and an oral consent form. The participant may only be included in the study after reviewing the information letter and giving oral consent, following a reflection period if necessary.

The patient’s receipt of information and their agreement to participate in the research must be recorded in their medical record.

7.9. FUNDING AND INSURANCE

The sponsor shall provide funding for the study and take out an insurance policy covering the financial consequences of its civil liability, in accordance with regulations.

7.10. RULES REGARDING PUBLICATION

The study will be registered on an open-access website (ClinicalTrials.gov) prior to the inclusion of the^{first}patient in the study.

The study may not be the subject of any written or oral commentary without the sponsor's consent; all information communicated or obtained during the conduct of the study belongs by right to the CHD Vendée, which may freely dispose of it.

All information resulting from this study is considered confidential, at least until the appropriate analysis and review by the sponsor, the study coordinator, and the study statistician have been completed.

Scientific communications and reports related to this study will be prepared under the responsibility of the study coordinator.

The coordinating investigator will be the primary signatory of the paper and the author of the documents; he or she must be listed as the first or last author. He or she may delegate this task to another person.

The coordinating investigator determines the list of authors. Investigators will be listed in proportion to the number of patients they recruited. The study statistician will also be listed.

Similarly, publications of ancillary results will include the name of the person who conducted the ancillary work as well as the names of all other individuals involved in that ancillary work.

All publications, abstracts, or presentations containing the study results must be submitted to the sponsor (CHD Vendée) for approval.
Publication guidelines will follow international recommendations (N Engl J Med, 1997; 336:309-315).

7.11. ARCHIVING OF SOURCE DATA

The investigator must retain all information related to the study for at least 15 years after the study's completion.

At the end of the study, the investigator will receive a copy of the data for each patient from their center, sent by the sponsor.

No removal or destruction may be carried out without the sponsor’s consent. At the end of the 15-year period, the sponsor will be consulted regarding destruction. All data, documents, and reports may be subject to audit or inspection.

8. BIBLIOGRAPHIC REFERENCES

1. Beaubrun En Famille Diant L, Sordes F, Chaubard T. Psychological impact of ostomy on the quality of life of colorectal cancer patients: role of body image, self-esteem, and anxiety. Bull Cancer 2018, Jun; 105: 573-580.

2. McKenna LS, Taggart E, Stoelting J, Kirkbride G, Forbes GB. The Impact of preoperative stoma marking on health-related quality of life: a comparative cohort study. J Wound Ostomy Continence Nurs. 2016 Jan-Feb; 43:57-61

3. Prieto L, Thorsen H, Juul K. Development and validation of a quality of life questionnaire for patients with colostomy or ileostomy. Health Qual Life Outcomes. 2005 Oct 12; 3:62

4. Garg PK, Goel A, Sharma S, Chishi N, Gaur MK. Protective Diversion Stoma in Low Anterior Resection for Rectal Cancer: A Meta-Analysis of Randomized Controlled Trials. Visc Med. June 2019;35(3):156–60.

5. Chaudhri S, Brown L, Hassan I, Horgan AF. Preoperative intensive, community-based vs. traditional stoma education: a randomized, controlled trial. Dis Colon Rectum. March 2005;48(3):504–9.

LIST OF APPENDICES

Appendix 1) Summary of the protocol

Appendix 2) Stoma-Qol Questionnaire

Appendix 3) Instructions for the component used for 3D printing of the stoma button