Towards the development of a personalized care pathway for patients with bowel symptoms after treatment for rectal cancer through precision medicine (TREATABLE)

A Data Management Plan created using DMPonline.be

Creators: Liesbet Lauwereins, n.n. n.n.

Affiliation: KU Leuven (KUL)

Template: KU Leuven BOF-IOF

Principal Investigator: n.n. n.n.

Project Administrator: Hans Vanderheyden

ID: 204417

Start date: 01-01-2024

End date: 12-01-2027

Project abstract:

Colorectal cancer is the 2nd and 3rd most common cancer in women and men, respectively and represents approximately 13% of all new cancer diagnoses, with 40% of cases specifically situated in the rectum. The gold standard treatment for rectal cancer (RC) is a low anterior resection, combined with chemoradiotherapy. However, given the improved oncological results, functional outcomes, such as bowel symptoms, become more and more important. Approximately 60-90% of RC patients are affected with a wide range of new onset bowel symptoms (incontinence for flatus or feces (solid, liquid), frequent bowel movements, urgency, clustering of defecation and evacuation problems) immediately after rectal treatment. The combination of these specific bowel symptoms and their impact on quality of life (QoL) has been summarized in an international consensus definition and is referred to as the Low Anterior Resection Syndrome (LARS).

Major LARS has an important impact on QoL and has major health economic consequences. This is attributable to its high prevalence after RC treatment, the chronic nature of symptoms and the limited evidence of available therapeutic options. This context leads to repetitive medical consultations, additional technical examinations which are often not very useful and need for prolonged medical treatment (multiple drug regimens), with often limited therapeutic gain. Furthermore, there is a lack of a comprehensive scoring system to identify the different aspects of LARS, leading to inadequate diagnostics and follow-up of symptoms.

Based on these considerations, there is a clear need for a comprehensive scoring system for identification of the different aspects of LARS and monitoring of therapeutic treatment.

The aim of this study is to develop a solid, patient-friendly and easy to interpret electronic bowel diary. This e-diary will be used to comprehensively map the complaints of patients, facilitating a prompt and effective approach to symptoms. In this way, it can contribute to improving the well-being of patients with rectal cancer and their surroundings in the healthcare process.

The first objective of this study is to extract items for a comprehensive bowel diary in patients with rectal cancer (Aim 1) based on a literature review (Aim 1a), a patient focus group (Aim 1b) and an international Delphi survey (Aim 1c). In this Delphi survey, a multidisciplinary group of experts and patients will score each item of the long list on a 1–9-point Likert scale from ‘Not Important’ (1) to ‘Essential’ (9) for inclusion in the bowel diary. Finally, a consensus meeting will be held for the participants who completed the Delphi survey (Aim 1d).

The subsequent objective of this study is to develop a new bowel diary (Aim 2). Based on the consensus meeting, a specific number of topics will be selected for inclusion in this bowel diary (Aim 2a). Thereafter, the bowel diary will be translated from English to Dutch (Aim 2b). The English and Dutch diary are then presented to a focus group of patients to assess content validity (Aim 2c). Subsequently, the e-diary will be developed (Aim 2d).

The third objective is to assess the usability (Aim 3a) and validity of the e-diary (Aim 3b), including construct validity, criterion validity, test-retest reliability and responsiveness.

Last modified: 14-02-2024

Towards the development of a personalized care pathway for patients with bowel symptoms after treatment for rectal cancer through precision medicine (TREATABLE)

Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Patientfocusgroup_1	Contact details of patients	N	D	N and T	.xlsx .csv	<1GB	/
Patientfocusgroup_2	Informed consent	N	P and D	T	On paper .pdf	<1GB	Stored in a folder in a locker
Patientfocusgroup_3	Interviews with patients	N	D	A	.mp4	<100GB	/
Patientfocusgroup_4	Personal and fieldnotes on interviews	N	P and D	T	On paper .pdf	<1GB	Written in a Notebook
Patientfocusgroup_5	Transcripts	N	D	T	.pdf	1-2GB	/
Patientfocusgroup_6	Coding of transcripts	N	D	T	.nvp (codes given in Nvivo)	<100GB	/
Delphi Survey_1	Contact details of patients	N	D	N and T	.xlsx .csv	<1GB	/
Delphi Survey_2	Contact details of experts	N	D	N and T	.xlsx .csv	<1GB	/
Delphi Survey_3	Informed consent	N	P and D	T	On paper .pdf	<1GB	Stored in a folder in a locker
Delphi Survey_4	Online questionnaire	N	D	N and T	.xlsx .csv	<1GB	/
Delphi Survey_5	Statistical data	N	D	N	.sps	<100GB	/
Consensus meeting_1	Meeting with experts and patients	N	D	A	.mp4	<100GB	/
Consensus meeting_2	Personal and fieldnotes on interviews	N	P and D	T	On paper .pdf	<1GB	Written in a Notebook
Content validity_1	Contact details of patients	N	D	N and T	.xlsx .csv	<1GB	/
Content validity_2	Informed consent	N	P and D	T	On paper .pdf	<1GB	Stored in a folder in a locker
Content validity_3	Interviews with patients	N	D	A	.mp4	<100GB	/
Content validity_4	Personal and fieldnotes on interviews	N	P and D	T	On paper .pdf	<1GB	Written in a Notebook

Content validity_5	Transcripts	N	D	T	.pdf	1-2GB	/
Content validity_6	Coding of transcripts	N	D	T	.nvp (codes given in Nvivo)	<100GB	/
Usability_1	Contact details of patients	N	D	N and T	.xlsx .csv	<1GB	/
Usability_2	Informed consent	N	P and D	T	On paper .pdf	<1GB	Stored in a folder in a locker
Usability_3	Online questionnaire	N	D	N and T	.xlsx .csv	<100GB	/
Usability_4	Statistical data	N	D	N	.sps	<100GB	/
Usability_5	Conversations with patients	N	D	A	.mp4	<100GB	/
Usability_6	Personal and fieldnotes on interviews	N	P and D	T	On paper .pdf	<1GB	Written in a Notebook
Usability_7	Transcripts	N	D	T	.pdf	<1GB	/
Usability_8	Coding of transcripts	N	D	T	.nvp (codes given in Nvivo)	<100GB	/
Psychometric properties_1	Contact details of patients	N	D	N and T	.xlsx .csv	<1GB	/
Psychometric properties_2	Informed consent	N	P and D	T	On paper .pdf	<1GB	Stored in a folder in a locker
Pychometric properties_3	Demographics	N	D	N	.xlsx .csv .redcap	<1GB	/
Psychometric properties_4	Clinical data (medical history)	N	D	N	.xlsx .csv .redcap	<1GB	/
Psychometric properties_5	E-diary in an app on mobile phone	N	D	N and T	.xlsx .csv .redcap	<100GB	/
Psychometric properties_6	Questionnaires	N	D	N	.xlsx .csv .redcap	<1GB	/
Psychometric properties_7	Statistical data	N	D	N	.sps	<100GB	/

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

Not applicable

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

The trial will be conducted in compliance with the principles of the Declaration of Helsinki (current version), the principles of GCP and in accordance with all applicable
regulatory requirements.
We have submitted this project for ethical review (S68746), but have not yet received a decision.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

We work with personal data at KU/UZ Leuven and has registered our study in the ethical review procedures: GDPR questionnaire UZ Leuven and the Privacy & Ethical (PRET) application. The approval number is G-2024-7654.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

Contact details of patients and experts, informed consents, personal and fieldnotes on interviews, interviews with patients, meeting with experts and patients will be stored in a separate password-protected file on the secured KU Leuven's one drive managed by KU Leuven, only accessible to the study staff.
Informed consents, personal and fieldnotes on interviews will be stored in a locker inside a locked room, only accessible to the study staff.
Demographics, clinical data (medical history), data derived from the bowel diary application and data derived from the questionnaires (LARS-score, criterion validity) will be gathered via the Research Electronic Data Capture (RedCap).
A readme.txt file in every folder explaining the structure and content of the data. Structure will be logged in REDCap.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- Yes

Metadata standards imbedded in REDCap will be used.
REDCap has the ability to export an entire REDCap project (its metadata of forms and events, as well as its data) as an XML file in CDISC ODM format. New projects can

also be created in REDCap using an ODM metadata file that has originated from REDCap itself or from any other ODM-compatible system.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Other (specify below)
- OneDrive (KU Leuven)

All data will be stored and organized with the electronic application REDCap (Research Electronic Data Capture). It is a web-based software and tool set that
allows researchers to create secure online forms for data capture, management and analysis. It is already widely used in many academic medical centers. Data will be
stored for at least 25 years. All study related documents will be collected on the OneDrive.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Data will be stored and automatically backed up in REDCap and the server of KU Leuven. The REDcap server is hosted and managed by the KU Leuven ICT department.
The data is backed up on a daily basis in addition to daily snapshots of the server. The backups and snapshots are retained for a period of 14 days.

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

Yes, the KU Leuven provides hosting for the REDcap application and will provide sufficient storage.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Authentication is based on a personal username and password, using the KU Leuven's Active directory server for authentication. Authorisation in REDcap is granted on a
project basis through REDcap's internal authorisation mechanism.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Data are stored in REDcap. The costs for the hosting and licence for REDcap is 80 euro each year covered by project funding.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans

All data will be stored for a period of 25 years in KU Leuven RDR. If the application will be taken out of commission before this period and without a datamigration to a new
platform, data will be exported to .csv. and ODM XML, an XML format for exchanging and archiving clinical data, associated metadata and audit information.

Where will these data be archived (stored and curated for the long-term)?

- KU Leuven RDR

The data will be stored in KU Leuven RDR, which is hosted in the datacenter of the KU Leuven. Should the application be taken out of commission, the data will be exported to
.csv and ODM XML and stored in a secure archive or file server.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

The cost of storing the data in REDcap will be covered by the KU Leuven.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

All pseudonymized data will be made available after the project upon request by mail.

If access is restricted, please specify who will be able to access the data and under what conditions.

All pseudonymized data will be made available after the project upon request by mail.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- No

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- Other (specify below)

Upon request by mail

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

Data can only be used after approval by the PI and after setting up a data transfer agreement between KU Leuven and the other party.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- No

What are the expected costs for data sharing? How will these costs be covered?

No costs are expected.

Responsibilities

Who will manage data documentation and metadata during the research project?

Inge Geraerts, André D'Hoore, Ellen Coeckelberghs, Liesbet Lauwereins

Who will manage data storage and backup during the research project?

Inge Geraerts, Ellen Coeckelberghs, Hans Vanderheyden, Liesbet Lauwereins

Who will manage data preservation and sharing?

Inge Geraerts, Hans Vanderheyden, Liesbet Lauwereins

Who will update and implement this DMP?

The PI bears the overall responsibility for updating & implementing this DMP.