ISRCTN13692671 https://doi.org/10.1186/ISRCTN13692671

The locally recurrent rectal cancer quality of life study

Submission date
18/12/2021

Recruitment status
No longer recruiting

Registration date
20/12/2021

Overall study status
Completed

Last Edited
15/01/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Locally recurrent rectal cancer is cancer that returns close to the origin site following surgery. The extent of the burden that locally recurrent rectal cancer has on quality of life is poorly reported. Patients with advanced cancer value both survival and quality of life. Using only traditional clinical endpoints in advanced cancer settings is no longer valid and should be reported alongside patient-reported outcomes such as quality of life, in an attempt to present a more balanced outlook on treatments and management strategies.

There are many questionnaires that currently exist that are used to assess quality of life, however, these tools have not been validated specifically for patients with locally recurrent rectal cancer. Validation means checking that the questionnaire is applicable across relevant patient groups. The LRRC-QoL is a questionnaire that has been designed specifically to assess quality of life in patients with locally recurrent rectal cancer. The LRRC-QoL has been developed and validated in patients from the UK and Australia.

The aims of the study are:
- to translate and validate the LRRC-QoL into 13 different languages to aid international research in determining the quality of life outcomes in locally recurrent rectal cancer,
- to understand the impact of locally recurrent rectal cancer and its treatment on quality of life,
- to identify survivorship issues relevant to patients who have undergone treatment for locally recurrent rectal cancer and are disease-free,
- to compare the quality of life outcomes between different groups of patients with locally recurrent rectal cancer.

Who can participate?
This study involves participants with locally recurrent rectal cancer.

What does the study involve?
There are three different parts of the study. The first part of the study aims to develop an international questionnaire that can be used to assess the quality of life in patients in patients with locally recurrent rectal cancer. This will involve a translation process followed by interviews with patients to ensure that the questionnaire is acceptable and understandable to them.

The second part of the study aims to measure quality of life in patients with locally recurrent rectal cancer. Quality of life will be assessed using the LRRC-QoL questionnaire at the start of the study, then at 3, 6, and 12 months. Participants will also be asked to complete three additional quality of life questionnaires at the start of the study which will be used in the analysis to ensure that the LRRC-QoL questionnaire is a valid measure of quality of life.

The third part of the study aims to identify the issues which are relevant to and impact upon the quality of life of survivors of locally recurrent rectal cancer. Taking part in this part of the study will involve a one-off interview with a researcher to identify the issues which are relevant to this group of patients.

What are the possible benefits and risks of participating?
The study will deliver wiser benefits as it will provide information regarding quality of life in patients with locally recurrent rectal cancer in many centres internationally. This information can be used to inform shared decision-making between patients and their medical team regarding their care. The study will also allow the LRRC-QoL to be used in future international research. There are no personal benefits to taking part in the study. The study will not affect or alter the treatment participants receive. Participants may find that completing the questionnaires causes them to experience emotional distress in reflecting upon their experience of locally recurrent rectal cancer.

Where is the study run from?
The study is run from the Clinical Trials Research Unit (CTRU) at the University of Leeds in the United Kingdom.

When is the study starting and how long is it expected to run for?
October 2020 to December 2024

Who is funding the study?
The study is funded by Bowel Research UK and Pelican Cancer Foundation (UK)

Who is the main contact?
Dr Niamh McKigney, N.McKigney@leeds.ac.uk

Study website
https://ctru.leeds.ac.uk/lrrc-qol/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272685

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 272685, CPMS 46607

Study information

Scientific Title
Health-related Quality of Life and survivorship in Locally Recurrent Rectal Cancer. The LRRC-QoL study

Acronym
LRRC-QoL

Study objectives
The clinical and oncological outcomes associated with locally recurrent rectal cancer and its various treatment modalities are well documented, however, there is a lack of high-quality, robust data on patient-reported outcomes of health-related quality of life using validated measures in this cohort of patients. Using traditional clinical endpoints alone in advanced cancer settings is no longer valid and such outcomes should be reported alongside patient-reported outcomes in an attempt to present a more balanced outlook on treatments and management strategies. This becomes more pertinent in this disease group as the treatment boundaries are continually pushed to enable ultra-radical resection to afford cure in a greater proportion of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2020, West of Scotland Research Ethics Committee 3 (Research Ethics, Clinical Research and Development, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44(0)1413140212; WoSREC3@ggc.scot.nhs.uk), ref: 20/WS/0116

Study design
International multi-centre longitudinal prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
https://ctru.leeds.ac.uk/lrrc-qol/patient-information/

Health condition(s) or problem(s) studied
Health-related quality of life and survivorship in locally recurrent rectal cancer

Interventions
The study has been designed as an international, multi-centre, mixed methods study. The study consists of 3 workstreams.

The first workstream will adapt the LRRC-QoL into a number of languages and for use in English-speaking countries outside of the UK and validate the measure in each participating country. This will involve a translation process followed by interviews with patients to ensure that the questionnaire is acceptable and understandable to them.

Workstream II is designed as a longitudinal, prospective observational cohort study and will consist of two parts. The first part will establish the reliability and validity of the LRRC-QoL in a large sample size within an international setting. The second part of the study will measure longitudinal outcomes in patients with locally recurrent rectal cancer over a 12-month period. Quality of life will be assessed using the LRRC-QoL questionnaire at the start of the study, then at 3, 6, and 12 months. Participants will also be asked to complete three additional quality of life questionnaires at the start of the study which will be used in the analysis to ensure that the LRRC-QoL questionnaire is a valid measure of quality of life.

Workstream III will identify survivorship issues in patients with locally recurrent rectal cancer. This part of the study will involve a one-off interview with a researcher to identify the issues which are relevant to this group of patients.

Intervention Type
Other

Primary outcome measure
Health-related quality of life assessed using the LRRC-QoL questionnaire at baseline, 10 - 14 days, 3, 6 and 12 months.

Secondary outcome measures
The survivorship issues relevant to patients who have undergone treatment for locally recurrent rectal cancer, these will be established through using qualitative interviews at a single time point.

Overall study start date
05/10/2020

Completion date
02/12/2024

Eligibility

Key inclusion criteria
Workstream I:
1.1 Aged over or equal to 18 years
1.2 Radiological and/or histological diagnosis of locally recurrent rectal cancer
1.3 Undergone treatment for locally recurrent rectal cancer within the last 2 years

1.4 Able to provide informed written consent to participate
1.5 Able to read and write in the target language.

Workstream II:
2.1 Aged over or equal to 18 years
2.2 New radiological and/or histological diagnosis of locally recurrent rectal cancer
2.3 Able to provide informed written consent to participate
2.4 Able to read and write in the target language.

Workstream III:
3.1 Aged over or equal to 18 years
3.2 Treated for locally recurrent rectal cancer and are disease-free for more than 3 years
3.3 Able to provide informed written consent to participate
3.4 Able to read and write in the target language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
320

Key exclusion criteria
1. Patients with cognitive impairment
2. Patients who are in remission from treatment of primary rectal cancer with no evidence of local recurrence
3. Patients who are receiving treatment for distant metastatic disease following previous treatment of rectal cancer with no evidence of local recurrence

Date of first enrolment
05/11/2020

Date of final enrolment
04/12/2023

Locations

Countries of recruitment
Australia

Brazil

Canada

Denmark

England

France

India

Ireland

Italy

Netherlands

New Zealand

Pakistan

Russian Federation

Scotland

Singapore

Spain

Sweden

United Kingdom

United States of America

Wales

Study participating centre
Manchester Royal Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
St Marks Hospital
St Marks Hospital
Watford Road

Harrow
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HA1 3UJ

Study participating centre
St James's University Hospital
St. James's University Hospital
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Leeds
United Kingdom
LS9 7TF

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Glasgow Royal Infirmary
84 Castle Street

Glasgow
United Kingdom
G4 0SF

Study participating centre
Leicester Royal Infirmary
Leicester Royal Infirmary
Infirmary Square
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United Kingdom
LE1 5WW

Study participating centre
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Nottingham University Hospital
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NG7 2UH

Study participating centre
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Bordesley Green
Birmingham
United Kingdom
B9 5ST

Study participating centre
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M20 4BX

Study participating centre
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United Kingdom
OX3 9DU

Study participating centre
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SO16 6YD

Study participating centre
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Dublin 4

Study participating centre
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33000 Bordeaux

Study participating centre
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Study participating centre
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Sahlgrenska University Hospital
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413 45 Göteborg
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Sweden
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Study participating centre
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Cleveland Clinic
9500 Euclid Avenue
Cleveland
United States of America
OH 44195

Study participating centre
MD Anderson Cancer Center
MD Anderson Cancer Center

1515 Holcombe Boulevard
Houston
United States of America
Texas 77030

Study participating centre
UC Davis Health
UC Davis Health
2335 Stockton Boulevard
Sacramento
United States of America
CA 95817

Study participating centre
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UNC Health Care
101 Manning Drive
Chapel Hill
United States of America
NC 27514

Study participating centre
Christchurch Hospital
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2 Riccarton Avenue
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Sengkang General Hospital
Sengkang General Hospital
110 Sengkang East Way
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Singapore 544886

Study participating centre
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Sher-i-Kashmir Institute of Medical Sciences

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India
190011

Study participating centre
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Study participating centre
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Hyderabad
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Study participating centre
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St Petersburg
Saint Petersburg
Russian Federation
199034

Study participating centre
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Moscow

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Russian Federation
119991

Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Bowel Research UK

Alternative Name(s)
Bowel Research United Kingdom, BRUK

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Pelican Cancer Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Niamh McKigney (N.McKigney1@leeds.ac.uk) the potential sharing of anonymised quality of life data for future health research purposes was included in the informed consent process.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No