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The role of an automated frailty score (electronic frailty index) in improving outcomes for cancer patients in chemotherapy

Submission date
14/10/2020

Recruitment status
No longer recruiting

Registration date
18/01/2021

Overall study status
Completed

Last Edited
21/08/2023

Condition category
Cancer

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

Plain English Summary

Background and study aims
Diagnosis of cancer is a fearful event for most people. Adequate information and provision of the best treatment can not be underestimated. The treatment of many cancers involves major interventions such as surgery, chemotherapy and radiotherapy. Treatment of people who are frail is even more challenging. Our health can be affected by cancer itself and a range of other conditions and it is really important that we balance the side effects of cancer treatment against the harms it can cause. We know from several studies that clinicians struggle with adequate assessment of older people living with frailty and with cancer and offer less aggressive treatment even if they are not frail. We also know that many frail and older patients suffer multiple side effects of treatment and sometimes die as a result of the treatment itself. We need an improved way of assessing frail patients with cancer. We believe it is possible to use a score that can be calculated from medical records that will help us to better estimate the risks of chemotherapy. This score is known as electronic frailty index (EFI) and has been useful in general practice. EFI is now automatically calculated by GPs from electronic medical records. To validate this type of score in cancer we need to undertake a research project in 2 parts.

Work-package 1 (Data analysis project):
Work-package 1 includes an analysis of historical systemic chemotherapy records (SACT). The SACT data will be obtained from Public Health England (PHE) and will include data for patients with stage II or III breast cancer, stage III colon cancer or stage IIIB-IV non-small-cell lung cancer (NSCLC) in England between January 1 2013 and December 31 2018. Patients with early breast cancer, stage III colon cancer as well as patients with NSCLC are considered for SACT and have improved survival as a result of SACT. We focus on this dataset as we have previously analysed these data and presented this at the NCRI conference . These data sets are already linked with some of the hospital records and survival data.

Data from SACT will be linked to Hospital Admissions statistics (HES data obtained from NHS-Digital) to calculate 30 day chemotherapy mortality for this cohort, hospital admissions during this time (starting day 1 cycle 1 to six months after day 1 cycle 1) as well as HES-EFI. HES-EFI will be calculated from the 35 fields that define EFI (full description in the attached protocol), with

the exception of polypharmacy. The NHS-digital data for linkage will be requested through Data Access Request Service online. Data will be pseudonymised and linked directly with researcher unable to access personal data of individual patients.

The data on EFI derived from GP records for the patients identified in the SACT dataset above will be obtained from the following databases:
- The Clinical Practice Research Datalink (CPRD)
- Royal College of General Practitioners (RCGP) Research and Surveillance Centre.
We have previously analysed 2013-2015 SACT data of patients with breast, lung and colorectal cancer and the results of this work have been presented at the NCRI conference. We plan to extend this analysis to include EFI, and compare the EFI derived from hospital data (HES-EFI) and the EFI derived from GP records (GP-EFI). This will be linked with 30-day chemotherapy mortality rates and hospital admissions during chemotherapy.30-day chemotherapy mortality is an accepted measure of poor outcome from chemotherapy and similarly the need to be admitted during chemotherapy often reflects the side effects of chemotherapy and is accepted as a measure of chemotherapy toxicity.

Work-Package 2 (Qualitative study)
Alongside the data analysis we will conduct a qualitative study that will examine patients, carers and clinicians' attitudes to using an automated frailty score that can influence the cancer treatment decision making process.

Who can participate?
Recruitment will only take place for Work-Package 2 (25 participants in total). Patients must have received at least one cycle of chemotherapy.
Carers who are the partner or child of the patient.
Stakeholders: Medical and Clinical Oncologists, General Practitioners, Geriatricians; Chemotherapy and Specialist Nurses
All participants must speak/ understand English and be willing to participate in an interview that will last between 30 and 45 minutes.

What does the study involve?
All participants (except GPs) for the qualitative part of the study, will be approached at St Luke's Cancer Centre based at the Royal Surrey County Hospital. Information about the study will be provided and then individuals will be invited to participate.
The semi-structured interviews will be audio-recorded, last approximately 30 – 45 minutes and will explore:
- Acceptability of using an electronic score to help with the chemotherapy risk calculation
- Appropriateness and acceptability of outcome measures for the future prospective study
- Acceptability of the randomisation process and recruitment process to the future prospective study
-The stakeholders will also be asked for their views regarding the design of the future prospective study and their views on how a frailty score could impact their decision-making process.

What are the possible benefits and risks of participating?
The main possible benefit of taking part is voicing your opinion on using an automated frailty score to influence the decision making process. There are no risks of participating.

Where is the study run from?
St Luke’s Cancer Centre at Royal Surrey County Hospital (UK)

When is the study starting and how is it expected to run for?
March 2020 to August 2022

Who is funding the study?
National Institute for Health Research (NIHR) Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Agnieszka Michael, A.michael@surrey.ac.uk

Study website
https://www.surrey.ac.uk/people/agnieszka-michael#research

Contact information

Type(s)
Scientific

Contact name
Dr Agnieszka Michael

ORCID ID
http://orcid.org/0000-0002-7262-6227

Contact details
University of Surrey
School of Biosciences
Leggett Building
Guildford
United Kingdom
GU2 7WG
+44 (0)1483688546
a.michael@surrey.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
279324

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20ONCN-279324, NIHR200517, CPMS 47050, IRAS 279324

Study information

Scientific Title
The role of Electronic Frailty Index in improving outcomes for newly diagnosed cancer patients undergoing systemic chemotherapy treatment

Acronym
EFI in Cancer

Study hypothesis
We believe that EFI can be successfully used as a tool to improve clinical decision making in frail cancer patients who undertake major anti-cancer treatment such as chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2020, Wales REC 6 (Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB, UK; +44 (0)1267 61 1164; Wales.REC6@wales.nhs.uk), ref: 20/WA/0284

Study design
Mixed methods study containing a qualitative study and a retrospective data review

Primary study design
Observational

Secondary study design
Qualitative study and a retrospective data review

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Condition
Cancer

Interventions
WP1 does not require patients' participation as the work undertaken will only relate to data obtained from electronic records. Anonymised medical records will be analysed to look for a link with electronic frailty index and poor outcomes from chemotherapy such as admission to hospital as a result of chemotherapy and dying as a result of chemotherapy.
Participants enrolled in the study described in work package 2 will be interviewed either in person or over the telephone and the interview will be recorded. Baseline information that will include the type of cancer, stage of cancer, age, gender, medical history and cancer treatment as

well as social circumstances and for health professionals - job title and description of the role, as well as length of time working in oncology, will be recorded. This will be the only intervention and following the interview participants will be discharged

Intervention Type
Other

Primary outcome measure
Work-package 1:
30 day chemotherapy mortality and hospital admissions during chemotherapy.
Information will be taken from historical systemic chemotherapy dataset (SACT) records 2013 - 2016 of patients with breast, lung and colorectal cancer. The data will be obtained from the following databases: The Clinical Practice Research Datalink (CPRD), ResearchOne database and Royal College of GPs (RCGP) Research and Surveillance Centre.

Secondary outcome measures
Work-package 2:
1. The acceptability of eFI (electronic frailty index) will be measured using interview data collected at a single time point that will be analysed with Framework Analysis
2. The suitability of the endpoints for a future definitive study - this will be decided once the data from WP1 shows the link between eFI and risk of dying from chemotherapy and risk of admission during chemotherapy. If eFI has a predictive power (the poorer the eFI score the higher the chance of complications) this will be deemed as a suitable endpoint for a future trial
3. The overall accuracy between hospital derived eFI and GP-medical records derived eFIGP-eFI) - the eFI and GP-eFI will be directly compared to assess the difference in score
4. The ease of access to GP-eFI and HES eFI - this will be a descriptive analysis of the time it takes to extract data and obtain relevant agreements

Overall study start date
01/03/2020

Overall study end date
31/08/2022

Eligibility

Participant inclusion criteria
1. Stakeholders (n=10)
1.1. 5 Medical and Clinical Oncologists, General Practitioners, Geriatricians
1.2. 5 Chemotherapy and Specialist Nurses
2. Patients (n=10)
2.1. 2 patients aged 60 - 70 with newly diagnosed stage II or III breast cancer and 2 >70 years old
2.2. 3 patients with stage 3 colon cancer (1 60 - 70 years old and 2 >70 years old)
2.3. 3 patients with Stage IIIB-IV non-small cell lung cancer (1 - 60-70 years old and 2 >70 years old)
3. Carers (n=5) Purposely selected for gender (men =3, women =2) and relationship to the patient (partner =3 or child =2)

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
25

Participant exclusion criteria
1. Stakeholders, patients or carers who do not fulfil the criteria described above
2. Are unable to participate in an interview
3. Do not speak/understand English

Recruitment start date
01/05/2021

Recruitment end date
02/05/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital
St Luke's Cancer Centre
The Royal Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

Sponsor details
Egerton Road
Guildford
England

United Kingdom
GU2 7XX
+44 (0)1483688546
alicegrant@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.royalsurrey.nhs.uk/

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V4.0	23/11/2020	08/02/2021	No	No
HRA research summary			26/07/2023	No	No