ISRCTN10401455 https://doi.org/10.1186/ISRCTN10401455

Establish and analyse a model of care for the management of people taking oral anti-cancer medications by an Advanced Nurse Practitioner: a pilot study

Submission date
27/10/2020

Recruitment status
No longer recruiting

Registration date
30/11/2020

Overall study status
Completed

Last Edited
01/03/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The introduction of oral medications to treat cancer is a new and welcome development in cancer management. These are called oral anticancer medications (OAM) and are an attractive option for patients. OAMs are being approved at record-setting pace over the past 3 years for oncology and are widely used in Ireland. Currently in Ireland, patients on OAM are being treated in hospital day units by consultants, and their specialist teams. Increased use of OAM has put significant pressure on acute oncology services and is unsustainable. To address these issues, the National Cancer Strategy 2017-2026 recommended the development of a model of care for OAM. Nurse-led clinics, either face-to-face or virtually using technology, have emerged as an ideal means to achieve safe convenient care for individuals on OAMs. Research shows high levels of patient satisfaction with such nurse-led care with a positive impact on patient outcomes, patient satisfaction and access to care. Health services are now focused on keeping people in their communities and the Irish Sláintecare report (2018) aims to deliver care closer to the person's home. This is particularly pertinent during the COVID-19 pandemic to minimize hospital visits. This study aims to establish a new model of care for this cohort of patients which concord with the 2018 National Cancer Control Programme OAM Model of Care Recommendations. This pilot study will assess the safety and efficacy of the proposed model of care.

Who can participate?
Patients with cancer currently taking OAMs

What does the study involve?
Phase 1 will describe the current ANP-led Oral Anti-cancer Medication (OAM) virtual clinics established in response to COVID-19 pandemic and this phase will last for up to 1 year. Phase 2 aims to produce a protocol for a pilot study of an improved version of the current virtual clinic which is fit for purpose with or without the COVID context. Taking part involves giving consent

for information on the individuals' healthcare to be collected for analysis. The participants will also be given the opportunity to share their opinions during group discussions (focus groups) or interviews to find out how the service can be improved.

What are the possible benefits and risks of participating?
A risk that potentially could occur is that a data breach that could cause an identity to be known, however, every effort will be made to maintain confidentiality in line with all data protection regulations. There is no direct benefit from participating in this study but information obtained may help direct the future management of patients on oral anti-cancer medication.

Where is the study run from?
Letterkenny University Hospital (LUH) and the National University of Ireland Galway (NUIG) (Ireland)

When is the study starting and how long is it expected to run for?
April 2020 to December 2022 (updated on 23/09/2022 from September 2022)

Who is funding the study?
Irish Cancer Society (Ireland)

Who is the main contact?
Dr Janice Richmond
janicep.richmond@hse.ie

Contact information

Type(s)
Public

Contact name
Dr Janice Richmond

Contact details
Oncology Department
Letterkenny University Hospital
Letterkenny
Ireland
F92 AE81
+353 (0)749123648
janicep.richmond@hse.ie

Type(s)
Scientific

Contact name
Prof Andrew Murphy

Contact details
National University of Ireland Galway
Galway
Ireland

-
+353 (0)91 524411
andrew.murphy@nuigalway.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CNRA19RICH

Study information

Scientific Title
Establish and analyse the safety and efficacy of an integrated care model for the management of patients receiving oral anti-cancer agents in the community by an Advanced Nurse Practitioner (ANP): a pilot study

Acronym
ARC

Study objectives
The aim of this study is to analyse the safety and efficacy of a virtual ANP-led clinic for patients receiving OAM established in response to COVID-19 and plan for eventual transition care from the virtual ANP clinic to the community, within the Irish healthcare system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/08/2020, Letterkenny University Hospital Ethics Committee (c/o General Managers Office, Letterkenny University Hospital, Co Donegal, Ireland; +353 (0)74 9123501; vanessa.savva@hse.ie), ref: not applicable

Study design
Collaborative multidisciplinary pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Individuals with cancer or taking oral anti-cancer medication (OAMs)

Interventions
This is a two-phase study, aiming to:
1. Design an ANP integrated oncology care model for the administration of OAM with input from local and national stakeholders and existing literature
2. Pilot test the feasibility, acceptability and costs of this model of care to inform the design of a future trial
The design of this study is based on the Development and Feasibility/piloting phases of the Medical Research Council (MRC) Framework for the development and evaluation of complex interventions to improve health

In consultation with local and national stakeholders and existing literature, the researchers will develop and refine this model of care. Focus groups/interviews will be conducted with healthcare providers and patients receiving OAMs, as this approach is appropriate for gathering different perspectives and to facilitate discussion, debate and problem-solving. Information collected on patients participating in this study will include a range of quantitative data. Attendance time, adverse events, adherence with taking medications as prescribed, frequency of contact with ANP are some of the data that will be collected. Questionnaires will be collected from participants to assess their health status, as well as their experience of the ANP model of care. Some patients will be asked to participate in one-to-one interviews with a member of the research team. The design of this study is based on the Development and Feasibility/piloting phases of the Medical Research Council (MRC) Framework for the development and evaluation of complex interventions to improve health. Use of the MRC framework ensures that a solid basis for an effective intervention is developed that is based on local knowledge and international evidence.

Intervention Type
Other

Primary outcome measure
1. Quality of life measured using the EQ-5D-5L questionnaire at baseline and 6-month follow-up
2. The experiences of patients and healthcare providers gathered using qualitative interviews /focus groups at one timepoint during the intervention

Secondary outcome measures
1. Quantitative data describing the intervention, e.g. patient waiting time, and intervention outcomes, e.g. adverse events and toxicity, gathered using study logs and predesigned forms. Toxicity grading system will be used throughout. The forms to capture the specific data will be

unique to this study and developed for its purpose. This data will be captured at each patient visit and will continue to be captured throughout the study period.
2. Healthcare resource use measured using questionnaire at baseline and 6-month follow-up

Overall study start date
08/04/2020

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Currently receiving an oral anti-cancer treatment
2. Have received OAM within 6 months of data collection commencing
3. Aged 18 years and over
4. Cognitively able to provide informed consent and complete the study activities
5. An ECOG performance status of 0-2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
37

Key exclusion criteria
1. Refusal to participate
2. Patients not taking oral anticancer medication.

Date of first enrolment
13/09/2020

Date of final enrolment
14/06/2021

Locations

Countries of recruitment

Ireland

Study participating centre
Letterkenny University Hospital
Oncology Dept
Letterkenny
Ireland
f92 ae81

Sponsor information

Organisation
Irish Cancer Society

Sponsor details
Northumberland Road, Dublin 6
Dublin
Ireland
Dublin 6
+353 (0)12310500
research@irishcacner.ie

Sponsor type
Charity

Website
http://www.cancer.ie/#sthash.HEWHm6I3.dpbs

ROR
https://ror.org/03844ds60

Funder(s)

Funder type
Charity

Funder Name
Irish Cancer Society

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Publication and dissemination plan
Results will be shared with the study sponsor (Irish Cancer Society) and the National Cancer Control Programme and planned publication in a high-impact peer-reviewed journal.

Intention to publish date
14/09/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	Results of phase I and protocol for phase II	24/02/2022	23/09/2022	No	No
Results article	Qualitative study	19/10/2022	20/10/2022	Yes	No
Results article		29/02/2024	01/03/2024	Yes	No