ISRCTN18388825 https://doi.org/10.1186/ISRCTN18388825

Barriers and facilitators to deprescribing antithrombotic therapy in advanced cancer patients: A qualitative interview study of patients', companions' and clinicians' experiences and perspectives

Submission date	**Recruitment status**	[X] Prospectively registered
30/01/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

For some patients with cancer, medicine given to thin the blood (known as antithrombotic therapy) can have some negative effects (such as excessive bleeding) and this can have an effect on their quality of life and well-being. Doctors might suggest that stopping this medicine could be helpful for some patients if they became further unwell with cancer, but what patients think about this is important. In addition, patients and their families/loved ones will need information and support to help them understand the risks and benefits of both continuing or stopping this medicine. However, firstly, we need to understand what the views and experiences of patients are around this subject, as well as that of their clinicians, as their current views and experiences are unknown. The results of these interviews will lead to the next stage of a larger study, which will be the development of an app. This app will contain information and support to help future cancer patients make choices about continuing or stopping this medicine in partnership with their doctors (known as shared-decision making).

Who can participate?

Patients who have cancer and are currently taking medicine to thin their blood (known as antithrombotic therapy) either due to a heart condition or they have developed a blood clot as a result of their cancer. Patients may include a companion to take part with them should they wish to do so. Clinicians will also be interviewed, from a variety of specialities involved in the management of these patients.

What does the study involve?

A 30-60 minute interview to explore experiences, values and perspectives on antithrombotic therapy at the end of life.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part, however, views and experiences will be used to inform the development of a shared decision-making app to help future patients make joint decisions about continuing or not continuing their antithrombotic medicine near the end of life. There are no anticipated risks to participating, participants will take part in one 30-60 minute interview. Topics discussed may result in some distress, however, this will be managed by experienced qualitative researchers. Taking part does not have any influence or impact on their existing care/treatment.

Where is the study run from?
This study is being carried out across Europe (UK, Denmark, Spain and France) to get the perspectives of patients with cancer and clinicians from these countries. Each research institution is responsible for carrying out the research separately and has its own research approvals in place.

When is the study starting and how long is it expected to run for?
September 2022 to October 2024

Who is funding the study?
INNOVATE UK/Horizon Europe

Who is the main contact?
Prof Simon Noble (Chief Investigator), NobleSI1@cardiff.ac.uk (UK)

Contact information

Type(s)
Principal investigator

Contact name
Prof Simon Noble

ORCID ID
https://orcid.org/0000-0001-5425-2383

Contact details
3rd Floor Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)2920687500
NobleSI1@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr Anette Arbjerg Hojen

ORCID ID

https://orcid.org/0000-0002-3851-3069

Contact details
Department of Cardiology
Aalborg University Hospital
Niels Jernes Vej 10
Aalborg
Denmark
9220
None provided
a.wind@rn.dk

Type(s)
Public

Contact name
Prof Annmarie Nelson

ORCID ID
https://orcid.org/0000-0002-6075-8425

Contact details
8th floor
Neuadd Meirionnydd
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)29 2068 7473
NelsonA9@cardiff.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323195

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
10039823, IRAS 323195

Study information

Scientific Title

Barriers and facilitators to deprescribing antithrombotic therapy in advanced cancer patients: A qualitative interview study of patients', companions' and clinicians' experiences and perspectives

Acronym
SERENITY

Study objectives
The aim of this qualitative study is to explore what influences the current practice of continuing and deprescribing antithrombotic therapy in cancer patients and identify potential barriers and facilitators to changing antithrombotic therapy at the end of life from the perspective of patients and clinicians.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 24/02/2023, London South East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 2071048120; approvals@hra.nhs.uk), ref: 23/PR/0115

2. approved 28/10/2022, The study is part of North Denmark Region's record of processing activities (ID No. F2022-157). Other approvals are not necessary according to Danish legislation (Forskning, Uddannelse og Innovation, Forskningsdata og Statistik, Sdr. Skovvej 15, Aalborg, 9000, Denmark; -; forskningsanmeldelse@rn.dk), ref: F2022-157

3. approved 29/05/2023, Comite de Etica de la Investigacion con medicamentos del Hospital Clinic de Barcelona (Hospital Clinic De Barcelona, Villarroel, Barcelona, 170-08036, Spain; -; cfont@clinic.cat), ref: HCB/2023/0336

4. approved 28/04/2023, Comité de protection des personnes Ile de France I (Hopital Hotel Dieu - 1, place du Parvis Notre dame, Paris, 75004, France; +33 142348052; cppidf1.htd@aphp.fr), ref: CPPIDFI-2023-DI24-Cat3

Study design
Qualitative interview study

Primary study design
Other

Study type(s)
Other

Health condition(s) or problem(s) studied
Cancer and deprescribing antithrombotic therapy at end-of-life

Interventions
Intervention
A qualitative study design to gain insight and a deeper understanding of patients' and clinicians' experiences and perceptions of continuing and deprescribing antithrombotic therapy. This will be explored using semi-structured interviews with patients and clinicians, at one time point,

using a semi-structured interview guide, and will last between 30-60 minutes. The interviews will be analysed using framework analysis.
The decision whether to continue or to deprescribe antithrombotic therapy in patients with cancer at the end of life is not clear since both options bring with them competing risks and advantages. Key factors in decision-making include the views of patients, their companions, if present, and clinicians. Currently, experiences and perspectives informing their stance are unknown. This interview study aims to gain insight from patients and clinicians on this topic. The results (anonymous) will inform future stages of a larger programme of work.
Patient participants will be identified by their lead consultant and approached by them during a routine clinical appointment and provided with a participant information sheet. Patient participants will be given a minimum of 24 hours to consider the information and are invited to have a companion take part with them. If the patient is interested, they can let their consultant know, or directly contact the researchers. An interview will be arranged at a time and mode of their choosing (face-to-face or remote). This may be at their home, at a hospital site or over telephone/remote video software (e.g. Zoom). A minimum of 15 patients will be recruited per participating country. In the event of participant distress due to discussion of sensitive topics, or if a clinical issue emerges, the researchers, using their experience, will react at the time and will refer the issue to the participants' clinical team, with their permission.
Clinician participants will be sampled from different specialities and will be identified as eligible and recruited through hospital management or hospital directories and invited by email to participate, with the participant information sheet. A total of 18-24 clinicians per participating country will be recruited, from the following specialities: Oncology, Care of the Elderly (Geriatrics), Frailty, Stroke Medicine, Palliative/Hospice Care, General Practitioner, Cardiology, Respiratory Medicine, and Vascular surgery. Interviews will be undertaken at participants' preferred location – face-to-face at a hospital site, or remotely, over video software or telephone.
Informed consent will be obtained from all participants prior to the interview, and participants will be made clear they can withdraw at any point. The researcher will take consent and conduct the interview. All interviews will be audio recorded; the recordings will be stored securely in locked files held within university servers, with restricted access. Audio files of the interviews will be transcribed verbatim by a member of the research team or a trusted, approved transcription agency. Transcripts will be anonymised prior to data analysis. Consent forms will also be stored securely, separate from anonymised transcripts. The participant information sheet contains detailed information on the confidentiality and data protection of data obtained during the interview, including how it will be stored, and how their anonymised data will be used /disseminated. The protocol will have the favourable opinion of a Research Ethics committee, as well as R&D approval from the recruiting sites prior to any research activity.
The interview transcripts (which will have been anonymised before analysis) will be analysed using framework analysis. Framework analysis was developed for use in applied policy research where objectives are clearly set and shaped by specific outcome needs with the intention of developing actionable outcomes and providing answers. NVivo 12 will be used as a data management tool to assist the analytical process. The themes and sub-themes identified will be displayed/summarised in a framework.

Intervention Type
Other

Primary outcome(s)
Outcome variables are measured using a 30-60 minute interview at one time point:
1. Cancer patients' (and companions' if present) experiences, values, and perspectives on antithrombotic therapy measured using a semi-structured interview guide

2. Clinicians’ experiences of the current practice of continuing and deprescribing antithrombotic therapy to cancer patients, and their perceptions of key facilitators and barriers to deprescribing measured using a semi-structured interview guide

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/10/2024

Eligibility

Key inclusion criteria
Patients:
1. Aged 18 years old and over
2. Advanced cancer (whose life expectancy is less than one year, according to the healthcare professional identifying eligible participants)
3. Receiving antithrombotic medicine for one of the following diseases: atrial fibrillation/stroke prevention, mechanical heart valve, peripheral vascular disease, and deep vein thrombosis or pulmonary embolus
4. Capacity to give informed consent
5. Capacity to undertake an interview in English

Companions:
1. Companions are defined as person(s) who look after and/or support the patient as identified and chosen by the patient to take part alongside them, should the companion wish to do so
2. Aged 18 years old and over
3. Capacity to give informed consent
4. Capacity to undertake an interview in English

Clinicians:
Clinicians practising in their chosen speciality for 10 years or more, from across the following specialities: oncology, care of the elderly, frailty, stroke medicine, palliative/hospice care, family physician/general practice, cardiology, respiratory medicine, and vascular surgery

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

Patients and companions:
1. Cognitive impairment
2. Unable to speak or understand English
3. Considered too unwell to participate in a 30-60 minute interview

Date of first enrolment
01/04/2023

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
United Kingdom

Wales

Denmark

France

Spain

Study participating centre
Aneurin Bevan UHB
Headquarters
St Cadoc's Hospital
Lodge Road
Caerleon
Newport
United Kingdom
NP18 3XQ

Study participating centre
Cardiff and Vale UHB
Cardigan House
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre

Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

Study participating centre
Aalborg University Hospital
Department of Oncology
Hobrovej
Aalborg
Denmark
18-22, 9000

Study participating centre
Aalborg University Hospital
Hobrovej
Aalborg
Denmark
18-22, 9000

Study participating centre
Hospital Clinic de Barcelona
Medical Oncology Department
Institut Clinic de Malalties Hematològiques i Oncològiques (ICMHO)
Institut per a la Recerca Biomèdica August Pi i Suñer (IDIBAPS)
Villarroel street 170
Barcelona
Spain
08036

Study participating centre
Hopitaux de Paris
3 Victoria Avenue
Paris
France
75004

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Organisation
Aalborg University Hospital

ROR
https://ror.org/02jk5qe80

Organisation
Hospital Clínic de Barcelona

ROR
https://ror.org/02a2kzf50

Organisation
Assistance Publique – Hôpitaux de Paris

ROR
https://ror.org/00pg5jh14

Funder(s)

Funder type
Government

Funder Name
Innovate UK/Horizon Europe

Alternative Name(s)
UK Research and Innovation Innovate UK, innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes