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Development of a predictive model for treatment decision making in older people with cancer

Submission date 14/08/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/08/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 08/10/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Cancer treatment involves an emotional and economic burden, with repercussions and costs that affect individuals, their families, and communities, as well as the health system and the country as a whole, which is why the Government considers cancer as a social problem, creating a National Cancer Plan that considers a financial protection system for high-cost diagnoses and treatments. This highlights the significance of the issue at the public policy level.

From this perspective, innovation can offer a solution to the current problem, which is why we propose to investigate, develop and validate the PROTEGER platform, through the research, development and validation of machine learning models in an unprecedented way worldwide to predict oncological treatments in older people with cancer with the design and development of the user experience, graphic interface, capable of being used by health users (doctor, nurse, technician, patient); and technically validate the PROTEGER software, capable of suggesting a 3-level onco-geriatric treatment recommendation (receives treatment, does not receive treatment or receives adjusted treatment).

Who can participate?

Elderly people (65 years and older) with a diagnosis of oncological pathology of solid tumour. Presented to a local oncology committee or local oncology team and has a chemotherapy indication and in whom a Comprehensive Geriatric Assessment (CGA) is performed.

What does the study involve?

A group of geriatricians and oncologists from various public and private healthcare centres in Chile, who are part of the research team, will use retrospective data to create, develop, and perform an initial validation of a model developed using machine learning techniques.

In a prospective cohort, the researchers will invite all older people with cancer who meet the inclusion criteria and have received a CGA and were presented to an oncogeriatrics committee as part of their health care in the context of oncological treatment.

Older people who consciously and informedly agree to participate in the study will provide the data obtained from their CGA for this research.

At 3 and 6 months the treating doctor will follow up with the participant and will check the

clinical record. Additionally, a telephone call will be made to the patient by a member of the research team, different from the treating physician, masked to the recommendation of the oncogeriatrics committee.
The information from the CGA, 3-month and 6-month follow-up will be recorded in a data recording platform for the researchers in charge of analyzing the information.
This information will help to develop, train and validate a predictive model with machine learning techniques to generate treatment recommendations to assist the decision-making of oncology teams according to the original indication of the oncogeriatrics committee, and design and develop an intuitive graphical interface for users (medical staff and patients) that allows data management and interpretation of analysis results.

What are the possible benefits and risks of participating?
The benefits are mainly for those with solid cancer who do not have access to an oncogeriatric committee and do not have the opportunity to get an expert recommendation about their cancer treatment.

Where is the study run from?
The study will run in different public and private centres in Chile

When is the study starting and how long is it expected to run for?
April 2024 to December 2026

Who is funding the study?
The cohort study follow-up does not have financial support
The development, training and validation of a predictive model with machine learning techniques is funded by CORFO CREA Y VALIDA (23CVC-245919) (Chile)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
PROTEGER: PROgrama de Tamizaje y Evaluación oncoGERiátrica (Oncology Screening and Evaluation Program)

Acronym
PROTEGER

Study objectives
The measurements obtained from the Comprehensive Geriatric Assessment (CGA) of older people with cancer and the decisions of an oncogeriatrics committee allow the development and training of a predictive model with machine learning techniques that provide treatment recommendations to assist the decision-making of oncology teams

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/04/2024, Scientific or Research Ethics Committee of the Clinical Hospital of the University of Chile (999 Dr Carlos Lorca Tobar Street, Santiago de Chile, 8380456, Chile; +56 229789008; comiteetica@hcuch.cl), ref: 1417/24

Study design
Multicentre mixed cohort (retrospective and prospective) study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Older people with oncological pathology (solid tumor)

Interventions
Current interventions as of 08/10/2025:
Data from older people with oncological pathology will be used.
All of them have received a comprehensive geriatric assessment at their respective centres and

are presented to an oncogeriatrics committee.
There will be two types of data: data from retrospective cohorts to create and develop a model, and data for initial validation.
The data from the prospective cohorts will include patients who meet the eligibility criteria and who give informed consent to participate.
The study will use their baseline characteristics, the results of their CGA, the clinical data related to oncological treatment, and the follow-up data at 3 and 6 months for the exclusive purpose of this research, specifically to validate a predictive model using machine learning techniques created with the retrospective data.

Previous interventions:
Older people with oncological pathology will be recruited.
All of them have received a comprehensive geriatric assessment at their respective centres and are presented to an oncogeriatrics committee.
All patients who meet the eligibility criteria and gave informed consent to participate will be selected
We will use their baseline characteristics, the results of their CGA, the clinical data related to the oncological treatment and the follow-up at 3 and 6 months for the exclusive purposes of this research for the development and validation of a predictive model with machine learning techniques.

Intervention Type
Other

Primary outcome(s)
The Machine Learning model performance will be evaluated with the Area Under Receiver Operating Characteristic Curve (AUC) compared to the decision of the Oncogeriatric team (no treatment, adjusted treatment, standard treatment).

Key secondary outcome(s))
3 and 6 months of follow up after the decision of the oncogeriatrics committee:
1. Longitudinal analysis of the patient quality of life measured using EORTC-QLQ-C30
2. Consultations to the Emergency Department and Hospitalisations measured using patient records
3. Adverse drug reaction measured using patient records
4. Treatment withdrawal measured using patient records
5. Chemotherapy dose delay or dose reduction measured using patient records
6. Functionality (Basics and Instrumental activity daily living measured with the Barthel Index and the Pfeffer test).
7. The ECOG Performance Status Scale.
8. Cognitive impairment measure The Telephone Screening of Cognitive Status (TICS), IQCODE
9. Overall survival and progression-free survival analysed by Kaplan–Meier survival and measured from patient records

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. People 65 years or older
2. Diagnosis of oncological pathology of solid tumours
3. The clinical case is presented to a local oncology committee or local oncology team
4. Patients in whom a CGA is performed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
110 years

Sex
All

Key exclusion criteria
Patients who do not have the capacity or do not wish to consent to the delivery of information

Date of first enrolment
01/06/2024

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
Chile

Study participating centre
Hospital Clinico Universidad de Chile
999 Dr. Carlos Lorca Tobar Street
Santiago de Chile
Chile
8380456

Study participating centre

Hospital San Juan de Dios
3255 Huérfanos Street
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Hospital Dr. Franco Ravera Zunino
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Sponsor information

Organisation
Hospital Clínico de la Universidad de Chile

ROR
https://ror.org/02xtpdq88

Organisation
Fundación Arturo López Pérez

ROR

https://ror.org/03r4w0b84

Funder(s)

Funder type
Government

Funder Name
Corporación de Fomento de la Producción

Alternative Name(s)
Corporation of Promotion of Production, Production Development Corporation, CORFO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request.
Contact: Dr Gonzalo Navarrete
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes