

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

Submission date 14/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/08/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 shows the importance of the problem 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 different public and private healthcare centres in Chile who are part of the research team will invite all older people with cancer who meet the inclusion criteria and 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 2025

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 founded by CORFO CREA Y VALIDA (23CVC-245919) (Chile)

Who is the main contact?

Dr Gonzalo Navarrete

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

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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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

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

Older people with oncological pathology (solid tumor)

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 measure

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).

Secondary outcome measures

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

Overall study start date

17/04/2024

Completion date

31/12/2025

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

Age group

Senior

Lower age limit

65 Years

Upper age limit

110 Years

Sex

Both

Target number of participants

412

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
Santiago de Chile
Chile
8350488

Study participating centre**Fundación Arturo López Pérez**

805 José Manuel Infante Street, Providencia
Santiago de Chile
Chile
7500921

Study participating centre**Hospital Dr. Hernán Henríquez Aravena -**

115 Manuel Montt Street
Temuco
Chile
4781151

Study participating centre**Hospital Regional de Antofagasta**

5935 Azapa Av.
Antofagasta
Chile
1240835

Sponsor information

Organisation

Hospital Clínico de la Universidad de Chile

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.redclinica.cl/>

ROR

<https://ror.org/02xtpdq88>

Organisation

Fundación Arturo López Pérez

Sponsor details

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cec@falp.cl

Sponsor type

Hospital/treatment centre

Website

<https://www.falp.org>

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

Publication and dissemination plan

Algorithmic transparency will be promoted through the declaration and publication of the entire development and validation process of the instrument in scientific journals with high methodological rigour and peer review.

Intention to publish date

01/04/2026

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