Development of a Multivariable Model to Predict the Risk of Dose Delays following Chemotherapy

First published: 22/05/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS35413

Study ID

35414

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Cancer chemotherapy is administered to patients at fixed time points to incorporate a rest period to recover from adverse effects (AEs) and delays to recovery will result in delays to scheduled treatments. These treatment delays occur in over 10% of chemotherapy patients and cause both patient and service inconvenience. The aim of this research is to develop a prediction model to understand those patients most susceptible to dose delays, enabling clinicians to action any mitigation strategies. This study is a retrospective cohort study using chemotherapy prescribing data from 4 UK hospitals to develop and internally validate a risk prediction model. Predictor variables have been identified from the literature. These will be initially analysed by univariable analysis to understand their associations with outcome, dose delays. These variables will enable the development of a multivariable logistic regression model. The model will be tested for performance and internally validated.

Study status

Ongoing

Research institutions and networks

Institutions

UCL School of Pharmacy, University College London

United Kingdom

First published: 11/03/2010

Last updated: 21/04/2015

Institution | Outdated | Educational Institution | ENCePP partner

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Chambers Pinkie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/11/2017

Study start date

Actual: 22/05/2019

Data analysis start date
Planned: 29/05/2020

Date of interim report, if expected
Planned: 30/09/2020

Date of final study report
Planned: 30/11/2020

Sources of funding

- Other

More details on funding

National Institute of Health Research

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Risk prediction model development

Main study objective:

to develop and internally validate a risk prediction model to identify those patients that are at risk of dose delays.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Renal impaired

Hepatic impaired

Estimated number of subjects

3000

Study design details

Data analysis plan

We will develop risk prediction equations using the whole cohort of patients to predict the risk of a patient receiving a dose delay at cycle 2.A Multivariable logistic regression model will be used for the analysis as an appropriate method where outcomes are binary and independent variables are continuous, categorical or a combination. Initially, we will fit a full multivariable model containing all variables. Backward elimination will then be used to successively remove non-significant factors with p values of greater than 0.2. Continuous candidate predictors will be retained in their continuous form to avoid statistical power loss.The performance of the developed model will be summarised in the development datasets using calibration and discrimination. Model calibration determines performance in terms of the agreement between predicted outcome risks and those actually observed. To quantify the degree of optimism, we will undertake in internal validation.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prescription event monitoring, Chemotherapy prescribing systems

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No