rEaL-world pharmacokinetics of Immune Checkpoint InhibiTors (ELICIT)

Published: 07-07-2021
Last updated: 30-11-2024

To determine the real-world pharmacokinetics of ICIs.

Ethical review	Approved WMO
Status	Completed
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON51955

Source
ToetsingOnline

Brief title
ELICIT

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, NSCLC

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: zorgverzekeraars

Intervention

Keyword: immune-checkpoint inhibitor, pharmacokinetics

Outcome measures

Primary outcome

At multiple time points, blood samples will be obtained to determine the

following pharmacokinetic characteristics of ICIs:

- Trough concentration (Cmin)

- Peak concentration (Cmax)

- Clearance (Cl) at baseline (Clbl) and change in clearance (compared to Cl at

end of treatment) (ΔCl), e.g. by Bayesian estimation using established and

validated population pharmacokinetic models, as published by the manufacturer

- Volume of distribution (Vd)

Secondary outcome

n/a

Study description

Background summary

Real-world pharmacokinetic data from cancer patients treated with immune checkpoint inhibitors (ICIs) are sparse. Moreover, pharmacokinetic parameters may be associated with response to ICI treatment and may act as a predictive or early response biomarker.

Study objective

To determine the real-world pharmacokinetics of ICIs.

Study design

The current study will be a low-interventional cross-sectional pharmacokinetic study in NSCLC patients who are, or will be treated, with ICIs in line with

routine care.

Study burden and risks

The nature and extent of burden and risks associated with participation are considered negligible, since only a maximum of 75 mL of blood will be drawn from subjects. Approximately one-third will be drawn during routine blood sampling using an already present cannula. This study can, therefore, be considered a low interventional clinical trial. There will be no individual benefit from participation in this study. However, participation in this study will contribute to increased understanding of real-world pharmacokinetics of ICIs.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Treatment with the ICIs mentioned in paragraph 4.1
- Willingness and ability to provide written IC
- Age 18 years or older

Exclusion criteria

Since we aim to assess the real-world pharmacokinetics, we will not make use of any exclusion criteria.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-09-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Imfinzi
Generic name:	durvalumab
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Keytruda
Generic name:	pembrolizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Opdivo
Generic name:	nivolumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tecentriq
Generic name:	atezolizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Yervoy
Generic name:	ipilimumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-001509-66-NL
ClinicalTrials.gov	NCT04833075
CCMO	NL77286.091.21