Nurses Internal Contamination by Antineoplastic Drugs (CACIES)

First published: 31/07/2017

Last updated: 24/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19729

Study ID

45549

DARWIN EU® study

No

Study countries

☐ France

Study description

The increase of cancer incidence contributes to a growing number of administered chemotherapies in care services. These antineoplastic drugs are not selective in their mechanisms of action, affecting noncancerous as well as

cancerous cells, leading to several known side effects in treated patients. Health care professionals are increasingly exposed to antineoplastic drugs and can be potentially contaminated by these molecules. This is a key concern as part of assessment and occupational risk management in healthcare settings.Occupational Health and Safety Department, in collaboration with Clinical and Toxicology Laboratory of Bordeaux teaching hospital, developed analytical tools to assess this contamination in health care professional’s urines, and the new acquisition of a high-sensitivity measurement equipment (LC-MS/MS) improved assays methods in terms of sensitivity and detection limits.The main objective of the study is to assess internal contamination prevalence by the studied antineoplastic drugs (5-fluorouracil, cyclophosphamide, doxorubicin, ifosfamide, methotrexate) in nursing staff who administers these chemotherapies or is in charge of patients treated by these chemotherapies, in two French hospital centers: Bordeaux teaching hospital and IUCT-Oncopole of Toulouse (Institut Universitaire du Cancer de Toulouse), including about fifteen services selected on their use of these specific chemotherapies.The secondary objectives of the study are on the one hand, to describe for each of the five studied antineoplastic drugs the internal contamination prevalence in nursing staff, and concentration level associated to this contamination in contaminated nursing staff, and on the other hand, to identify contamination-associated factors in exposure characteristics and personal protective equipment use.This is a descriptive, multicentre, transverse and prospective study.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

University Hospital of Bordeaux Bordeaux, France, IUCT-Oncopole Toulouse Toulouse, France

Contact details

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Primary lead investigator

Catherine VERDUN-ESQUER

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/02/2016

Actual: 01/02/2016

Study start date
Planned: 11/09/2017

Actual: 16/10/2017

Data analysis start date
Planned: 22/03/2019

Actual: 17/07/2019

Date of final study report
Planned: 30/11/2019

Actual: 21/02/2020

Sources of funding

- Other

More details on funding

2013-Hospital Clinical Research Programme

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NCT03137641https://clinicaltrials.gov/ct2/show/NCT03137641?term=CACIES&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The main objective of the study is to assess internal contamination prevalence by the studied antineoplastic drugs (5-fluorouracil, cyclophosphamide, doxorubicin, ifosfamide, methotrexate) in nursing staff who administers these chemotherapies or is in charge of patients treated by these chemotherapies, in two French hospital centers: Bordeaux teaching hospital and IUCT-Oncopole of Toulouse.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Nursing staff who administers these chemotherapies or is in charge of patients treated by 5-fluorouracil, cyclophosphamide, doxorubicin, ifosfamide, methotrexate chemotherapies, in two French hospital centers: Bordeaux teaching hospital and IUCT-Oncopole of Toulouse (Institut Universitaire du Cancer de Toulouse).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

71

Study design details

Outcomes

Presence or absence of internal contamination by at least one antineoplastic drug of the five studied antineoplastic drugs (5-fluorouracil, cyclophosphamide, doxorubicin, ifosfamide, methotrexate) in at least one of the three urine samples collected by subject. -Contamination prevalence in nurses and concentration level for each of the 5 antineoplastic drugs,-Socio-demographic and occupational factors,-Procedures for handling antineoplastic drugs and for taking care patients treated by these drugs, -Personal protective equipment use (gloves...).

Data analysis plan

The statistical analysis will include a descriptive analysis of included nurses (distribution according to service, age, sex, seniority, etc....) The analysis of the primary endpoint will be the proportion of contaminated subjects by at least one antineoplastic drug (among the five studied ones) in at least one of the three urine samples collected by subject The analysis of the secondary endpoint will be based on:- for each antineoplastic drug, the proportion of contaminated nurses,- the description of the antineoplastic drugs handling procedures and of the management of patients,- the description of personal protective equipments conditions of use,- factors associated with the internal contamination of the nurses (multiple logistic regression model)These results will be described overall and stratified by service.

Documents

Study publications

Villa A, Molimard M, Sakr D, Lassalle R, Bignon E, Martinez B, et al. Nurses' i...

Villa A, Molimard M, Bignon E, Martinez B, Rouyer M, Mathoulin-Pelissier S, et ...

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)

Other

Data sources (types), other

Prospective patient-based data collection

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