

# Angiotensin II receptor blockers and risk of cancer after contamination with N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) (Sartans contamination -feasibility study)

**First published:** 22/10/2019

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS31895

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### Study ID

31896

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### DARWIN EU® study

No

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### Study countries

 Netherlands

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## Study description

This is a feasibility analysis to inform a potential epidemiological study of an association between exposure to contaminated sartans products and the occurrence of cancer. The study will calculate sample sizes needed to detect the estimated cancer risk and minimum excess risk, as well as identifying EU databases with enough information to allow the conduct of the study.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

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Study contact

[alexandra.pacurariu@ema.europa.eu](mailto:alexandra.pacurariu@ema.europa.eu)

### Primary lead investigator

Alexandra Pacurariu

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 01/09/2018

Actual: 01/09/2018

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### **Study start date**

Planned: 15/09/2018

Actual: 15/09/2018

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### **Date of final study report**

Planned: 11/02/2019

Actual: 11/02/2019

## Sources of funding

- EMA

## Study protocol

[Sartans feasibility study - protocol.pdf](#) (211.44 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Feasibility analysis

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objectives of this feasibility analysis are: • to estimate the sample size (number of exposed patients) that would be needed to identify an excess risk of cancer associated with sartans under different assumptions about the background rate of cancer in Europe and assumptions of the relative risk. • to

identify European population databases that would be appropriate to analyse this risk

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Sample size calculation

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(C09CA) Angiotensin II receptor blockers (ARBs), plain  
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### **Medical condition to be studied**

Malignant neoplasm of unknown primary site

## Population studied

### **Short description of the study population**

Patients who had received angiotensin II receptor blockers

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### **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)
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### **Estimated number of subjects**

16000000

## Study design details

### **Outcomes**

All types of cancer excluding non-melanoma skin cancer.

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### **Data analysis plan**

We will perform sample size calculation for a cohort study with two equal exposed arms, across a range of background risk estimates and relative risks.

## Documents

### **Study results**

[Sartans feasibility study - results .pdf](#) (440.38 KB)

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## Data management

## ENCePP Seal

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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)

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

No