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

Study ID

31896

DARWIN EU® study

No

Study countries

Netherlands

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 detected the estimated cancer risk and minimum excess risk, as well as identifying EU databases with enough information to allow the conduct of the study.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Alexandra Pacurariu alexandra.pacurariu@ema.europa.eu

Study contact

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

Study start date
Planned: 15/09/2018

Actual: 15/09/2018

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

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

Study type:

Non-interventional study

Scope of the study:

Feasibility analysis

Data collection methods:

Secondary use of data

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

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

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)

Estimated number of subjects

16.000.000

Study design details

Outcomes

All types of cancer excluding non-melanoma skin cancer.

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)

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)

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No