Antihypertensives/diuretics and skin cancer

First published: 10/07/2018

Last updated: 27/03/2023

Study Finalised

Administrative details

EU PAS number

EUPAS24772

Study ID

24773

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study aims to provide a review of existing available evidence regarding the association between hydrochlorothiazide (HCTZ) / anti-hypertensive drugs and non-melanoma skin cancer (NMSC) / malignant melanoma (MM), together with a quality appraisal of the existing studies

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

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/01/2018

Actual: 23/01/2018

Study start date

Planned: 23/01/2018

Actual: 23/01/2018

Date of final study report

Planned: 06/08/2018

Actual: 06/08/2018

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

This report aims to provide a review of existing available evidence regarding the association between HCTZ/ anti-hypertensive drugs and NMSC/MM, together with a quality appraisal of the existing studies.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09DX01) valsartan, amlodipine and hydrochlorothiazide

valsartan, amlodipine and hydrochlorothiazide

(C09BX03) ramipril, amlodipine and hydrochlorothiazide

ramipril, amlodipine and hydrochlorothiazide

(C09DX03) olmesartan medoxomil, amlodipine and hydrochlorothiazide
olmesartan medoxomil, amlodipine and hydrochlorothiazide
(C03AX01) hydrochlorothiazide, combinations
hydrochlorothiazide, combinations
(C03EA01) hydrochlorothiazide and potassium-sparing agents
hydrochlorothiazide and potassium-sparing agents
(C03AB03) hydrochlorothiazide and potassium
hydrochlorothiazide and potassium
(C03AA03) hydrochlorothiazide
hydrochlorothiazide
(C09XA54) aliskiren, amlodipine and hydrochlorothiazide
aliskiren, amlodipine and hydrochlorothiazide
(C09XA52) aliskiren and hydrochlorothiazide
aliskiren and hydrochlorothiazide

Population studied

Short description of the study population

The study focused on association between hydrochlorothiazide/anti-hypertensive drugs and non-melanoma skin cancer/malignant melanoma identified from the existing available evidence.

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

50.000

Study design details

Outcomes

malignant melanoma, non-melanoma skin cancer

Data analysis plan

To describe the type of studies, their characteristics and the variables used for confounding adjustment by them.

Documents

Study publications

Morales DR, Pacurariu A, Slattery J, Kurz X. Association between hydrochlorothi…

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)

Published literature

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