

Association between the Use of Hydrochlorothiazide and the Risk of Skin Cancers: A Population-Based Retrospective Cohort Study in Taiwan

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Study

Planned

Administrative details

EU PAS number

EUPAS47664

Study ID

47834

DARWIN EU® study

No

Study countries



Taiwan

Study description

This is a retrospective cohort study aimed to evaluate the risk of skin cancer among Asian patients exposed to hydrochlorothiazide for long-term use. The comparator groups would be the chronic user of other thiazide diuretics, non-thiazide diuretics, and other antihypertensive drugs. Also, we enrolled a general population from the database to serve as the background risk of skin cancer. By implementing the multivariable cox-proportional hazard model, we could evaluate the risk of skin cancer compared with a different active comparators.

Study status

Planned

Research institutions and networks

Institutions

National Cheng Kung University (NCKU)

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

Edward ,chia-cheng Lai

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2020

Study start date

Planned: 01/08/2021

Data analysis start date

Planned: 31/12/2021

Date of interim report, if expected

Planned: 31/12/2021

Date of final study report

Planned: 01/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-Aventis

Study protocol

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

The risk of non-melanoma skin cancer (NMSC) among patients received hydrochlorothiazide versus other antihypertensive agents.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C03AA03) hydrochlorothiazide

hydrochlorothiazide

Population studied

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

2000000

Study design details

Outcomes

NMSC is divided into squamous cell carcinoma and basal cell carcinoma,
Malignant melanoma

Data analysis plan

The survival analysis was implanted by the Cox-proportional hazard model and Kaplan-Meier method. The crude and adjusted hazard ratio between drug exposure and skin cancer outcome were calculated by univariate regression model and multivariate regression, respectively. In the multivariate regression model, including the baseline covariates into the stepwise selection process to identify the appropriate variables.

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 source(s), other

Natioanl Health Insuran Database Taiwan

Data sources (types)

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

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