Management of Urinary Tract Infections in Catalonia: adequacy of diagnostic and therapeutic management, predictors of complications and impact of suppressive therapies on the severity of potentially serious infections (PROJECT ITUCAT)

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/49725

EU PAS number

EUPAS49724

Study ID

49725

DARWIN EU® study

No

Study countries

Study status

Planned

Research institutions and networks

Institutions



Spain

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Contact details

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Primary lead investigator

Study timelines

Date when funding contract was signed Planned: 11/04/2022

Study start date Planned: 01/12/2022

Date of final study report Planned: 01/03/2024

Sources of funding

• Other

More details on funding

PERIS 2022-2024 grant (grants for the financing of research projects in the field of primary health care, of the Strategic Plan for Research and Innovation in Health), with the file code SLT021/21/000022.

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:

Disease epidemiology Drug utilisation

Main study objective:

- To know the epidemiology of the different types of UTI in Catalonia and their diagnostic and therapeutic management. - To evaluate the correlation between the total consumption and type of antibiotics for recurrent UTI with the presence and severity of infectious complications of urological origin (pyelonephritis and sepsis), and two potentially serious infections (pneumonia and COVID-19

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Urinary tract infection

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)

Special population of interest

Hepatic impaired Immunocompromised Pregnant women Renal impaired

Estimated number of subjects

1500000

Study design details

Data analysis plan

Descriptive statistics will be carried out on the results obtained. Quantitative variables will be described as mean and standard deviation, while categorical variables will be described as the proportion of exposed and unexposed individuals. Univariate tests will be obtained from Student's t-test and the chisquare test as appropriate. For the primary outcome, marginal structural models will be fitted to estimate causal effects by correcting for confounding. Inverse probability weights will be estimated as a function of propensity score using age and socioeconomic deprivation score. The inverse probability weights will be used in the marginal structural model to estimate the odds ratio and confidence intervals purchasing the prevalence of each outcome among individuals exposed to antibiotics versus those not exposed to antimicrobials.

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Disease registry 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