aggregate Gargano Mortality Study

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Data source | Human | Hospital inpatient records

Administrative details

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PURI

https://redirect.ema.europa.eu/resource/1111199

Data source ID

1111199

Data source acronym

aGMS

Data holder

Fondazione IRCCS Casa Sollievo della Sofferenza

Data source type

Hospital inpatient records

Main financial support

European public funding

National, regional, or municipal public funding

Care setting

Hospital inpatient care

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

No

Data source website

https://www.operapadrepio.it/it/ricerca-scientifica/gruppi-di-ricerca/endocrinologia

Contact details

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Main

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Data source regions and languages

Data source countries

Italy

Data source languages

English

Italian

Data source regions

Puglia

Data source establishment

Data source established

15/06/2003

Data source time span

First collection: 05/11/2000

The date when data started to be collected or extracted.

Publications

Data source publications

Serum resistin is causally related to mortality risk in patients with type 2 diabetes: preliminary evidences from genetic data

Serum Resistin and Multicytokine Inflammatory Pathway Is Linked With and Helps Predict All-cause Death in Diabetes

Circulating Metabolites Associate With and Improve the Prediction of All-Cause Mortality in Type 2 Diabetes

Development and validation of a predicting model of all-cause mortality in patients with type 2 diabetes

The Synergic Association of hs-CRP and Serum Amyloid P Component in Predicting All-Cause Mortality in Patients With Type 2 Diabetes

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

Disease details

Type 2 diabetes mellitus

Disease details (other)

Information collected about people affected by Type 2 Diabetes were: clinical data about comorbidities, family history of diabetes and/or cardiovascular disease, life-style habits, demographic and anthropometric features, diabetes duration and conventional blood exam panel, systolic and diastolic blood pressure, renal function, ongoing treatments for hypertension, dyslipidemia, hypertriglycemia, vital status and genetic data.

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

No

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

No

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Cause of death vocabulary

ICD-10

Prescriptions of medicines

Captured

Dispensing of medicines

Not Captured

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

Indication vocabulary

ICD-9-CM

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

Administration of vaccines

No

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

Procedures vocabulary

ICD-9-CM

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

No

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

Genetic data

Are data related to genotyping, genome sequencing available?

Captured

Genetic data vocabulary

HGNC

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

Yes

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

Yes

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-10

ICD-9-CM

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Medicinal product vocabulary

SNOMED

Quality of life measurements

Captured

Quality of life measurements vocabulary

Not coded (Free text)

Lifestyle factors

Captured

Lifestyle factors

Frequency of exercise

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Ethnicity

Gender

Quantitative descriptors

Population Qualitative Data

Population age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated percentage of the population covered by the data source in the catchment area

30%

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are

registered only for private care)

Registered only for private care and hospital outpatients.

Population

Population size

2140

Active population size

1074

Population by age group

Age group	Population size	Active population size
Adults (18 to < 46 years)	114	94
Adults (46 to < 65 years)	1143	727
Elderly (≥ 65 years)	707	219
Adults (65 to < 75 years)	678	224
Adults (75 to < 85 years)	196	28
Adults (85 years and over)	5	1

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

13.60

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt

15.00

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

https://www.operapadrepio.it/it/chi-siamo/organizzazione/comitato-etico

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

Yes

Biospecimen access conditions

Data may be requested to the Scientific contact. Agreements compliant with the provisions of the EU Regulation n. 2016/679 (GDPR) and Ethical Committee approvation is required. Link: https://www.operapadrepio.it/it/chi-

siamo/organizzazione/comitato-etico

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

Yes

Description of data collection

Data were collected on Microsoft Excel from paper format patient medical records and then transferred to SQL Server DBMS.

Event triggering registration

Event triggering registration of a person in the data source

Other

Event triggering registration of a person in the data source, other

Hospitalisation

Event triggering de-registration of a person in the data source

Other

Event triggering de-registration of a person in the data source, other

Upon request from the patient

Event triggering creation of a record in the data source

Patients are recorded at hospitalisation. There is not the possibilty to create new records as the clinical study is closed in terms of recruitment but follow up data regarding mortality and kidney funtion continue to be collected.

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

Yes

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

SISWeb

Linkage variable

ID code

Linkage completeness

All patients in the dataset has a corresponding record in the hospital Health Information System.

Data management specifications that apply for the data source

Data source refresh

Yearly

Informed consent for use of data for research

Required for all studies

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

Yes

Data source preservation

Are records preserved in the data source indefinitely?

Yes

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

Yes

Data source last refresh

12/02/2023

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data source ETL CDM version

5.4

Data source ETL frequency

12,00 months

Data source ETL status

Completed