Rhekiss: Rheuma - Kinderwunsch und Schwangerschaft

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Data source | Human | Disease registry

Administrative details

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Data source ID

1000000028

Data source acronym

Rhekiss

Data holder

Epidemiology Unit, Deutsches Rheuma-Forschungszentrum Berlin (DRFZ)

Data source type

Disease registry

Main financial support

Funding by own institution

Other

Care setting

Hospital outpatient care

Primary care – specialist level (e.g. paediatricians)

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://rhekiss.de/

Contact details

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Data source regions and languages

Data source countries

Germany

Data source languages

German

Data source establishment

Data source established

01/09/2015

Data source time span

First collection: 01/09/2015

The date when data started to be collected or extracted.

Publications

Data source publications

Pregnancy and neonatal outcomes in women with axial spondyloarthritis: pooled data analysis from the European Network of Pregnancy Registries in Rheumatology (EuNeP)

Mobile Responsive App—A Useful Additional Tool for Data Collection in the German Pregnancy Register Rhekiss?

European Network of Pregnancy Registers in Rheumatology (EuNeP)—an overview of procedures and data collection

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

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.

Yes

Pregnancy and/or neonates

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

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

MedDRA

Prescriptions of medicines

Captured

Prescriptions vocabulary

not coded

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?

Yes

Indication for use

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

Not Captured

Medical devices

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

No

Administration of vaccines

Yes

Procedures

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

Captured

Procedures vocabulary

MedDRA

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.

Yes

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?

Not Captured

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

Biomarker data vocabulary

Other

Biomarker vocabulary, other

Laboratory values, free text

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

MedDRA

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dosage regime

Medicinal product vocabulary

Not coded (Free text)

Quality of life measurements

Captured

Quality of life measurements vocabulary

other

Quality of life measurements, other

HAQ

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Education level

Gender

Marital status

Quantitative descriptors

Population age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

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

Cannot be distinguished since no prevalence data on pregnancies in women with inflammatory rheumatic diseases exist for Germany.

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)

Nation-wide collection of data from women with different inflammatory rheumatic diseases that are planning a pregnancy or are pregnant. Women are enrolled by rheumatologists in private practice or outpatient clinics of hospitals.

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Permanently

Family linkage available between the following persons

Mother-child

Population

Population size

3500

Active population size

750

Population by age group

Age group	Population size	Active population size
Infants and toddlers (28 days – 23 months)	1400	250
Adults (18 to < 46 years)	2100	500

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://rhekiss.de/

Biospecimen access

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

No

Access to subject details

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

Yes

Description of data collection

Electronic Case Report Forms (eCRF) are provided in a web-based system are filled in by the participating rheumatologist and woman. Via a pseudonymization service, personal data of the patient are de-identified before data is saved in the data storage server.

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

A woman with an inflammatory rheumatic disease can be registered if she wants to conceive or if she is already pregnant (up to gestational week 20).

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

Death

Loss to follow up

Practice deregistration

Event triggering creation of a record in the data source

Data is reported at regular follow-up visits. Before conception: every 6 months with a maximum observation of 2 years. During pregnancy: every trimester. Postpartum: every 6 months with a maximum observation of 2 years.

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?

No

Data management specifications that apply for the data source

Data source refresh

Every 6 months

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?

No

Data source last refresh

31/12/2023

Common Data Model (CDM) mapping

CDM mapping

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

No