Risk and course of COVID-19 infection in patients with hypo- or hyperthyroidism. A Danish population-based cohort study (Thyroid dysfunction and COVID-19 infection)

First published: 19/08/2020

Last updated: 11/03/2021

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39990

EU PAS number

EUPAS36804

Study ID

39990

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Background: At present there are no data regarding the risk and course of COVID-19 in patients with hypo- or hyperthyroidism. As hypo- and hyperthyroidism are quite common conditions any association with risk and prognosis of COVID-19 may have important public health impact. Thus, there is an urgent need to clarify whether there is an increased risk and/or worsened prognosis of COVID-19 in patients with hypo- or hyperthyroidism, using high quality population-based data. Objective: To examine the risk and course of COVID-19 in patients with hypo- and hyperthyroidism. Exposure: Hypo- and hyperthyroidism are defined as use of Levothyroxine and anti-thyroid drugs, respectively. Outcomes: Primary outcomes are death, hospitalization, intensive care unit admission within 30 days after a positive test for COVID-19. The secondary outcome is risk of COVID-19 in patients with hypo- or hyperthyroidism. Methods: Nationwide register based study including all persons tested for COVID-19 in Denmark (1.417.864, mid August 2020). The impact of hypo- and hyperthyroidism on risk of acquiring COVID-19 will be examined using a case-control design, while the prognosis will be evaluated in a cohort of COVID-19 positive patients. The odds ratio for hypo- and hyperthyroidism will be estimated using logistic regression models adjusted for age, gender, and comorbidity.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacoepi center, University of Southern Denmark

Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | Educational Institution | ENCePP partner

Department of Endocrinology, Odense University hospital, Sdr. boulevard 29, 5000 C Odense, Denamrkl Denmark

Contact details

Study institution contact

Thomas Brix

Study contact

thomas.brix@rsyd.dk

Primary lead investigator

Jesper Hallas

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 27/02/2020

Actual: 27/02/2020

Study start date
Planned: 27/02/2020

Actual: 27/02/2020

Data analysis start date
Planned: 01/10/2020

Date of final study report
Planned: 16/11/2020

Actual: 01/02/2021

Sources of funding

- Other

More details on funding

University of Southern Denmark

Study protocol

Protocol-version-7.docx.pdf(599.36 KB)

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 topic:

Human medicinal product

Disease /health condition

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:

To examine the risk and course of COVID-19 in patients with hypo- and hyperthyroidism

Study Design

Non-interventional study design

Cohort

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H03AA) Thyroid hormones

Thyroid hormones

(H03B) ANTITHYROID PREPARATIONS

ANTITHYROID PREPARATIONS

Medical condition to be studied

Hypothyroidism

Hyperthyroidism

COVID-19

Population studied

Short description of the study population

The source population is all Danish citizens, approximately 5.8 million. The study population for the risk of COVID-19 in patients with hypo- or hyperthyroidism will be all persons tested for SARS-CoV-2 in the study period. Only persons tested positive for SARS-CoV-2 will be included in the prognosis analysis (cohort analysis).

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

15000

Study design details

Outcomes

30-day mortality after positive RT-PCR for SARS-CoV-2 as identified using the Danish Register of Causes of Deaths.The risk of COVID-19 in patients with hypo- or hyperthyroidism. hospitalization, intensive care unit admission within 30 days after a positive test for COVID-19.

Data analysis plan

Propensity-score weighted risk, risk difference and risk ratio for the outcomes. Adjusted odds ratio for positive test among all tested.

Documents

Study results

Brix et al 2021 Lancet, COVID in thyroid disease.pdf(62.65 KB)

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

Danish Registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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