Influence of exocrine pancreatic insufficiency on the formation of uremic toxin indoxyl sulfate in patients in a dialysis program

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Study Planned

Administrative details

EU PAS number

EUPAS38785

Study ID

38786

DARWIN EU® study

No

Study countries

☐ Czechia

Study description

A monocentric, prospective, open cohort study was performed. The study group consisted of 27 anuric patients from a single hemodialysis center undergoing chronic renal replacement therapy. The aim was to test anuric patients by using a non-invasive breath test with 13C mixed triglyceride for subclinical pancreatic insufficiency. We corellated these results with the serum concentrations of indoxyl sulfate in the patients. The elimination of indoxyl sulfate by current dialysis strategies are very difficult and only partial, it is necessary to consider the possibility of influencing the formation of indoxyl sulfate in vivo by reducting the residual protein entering the colon.

Study status

Planned

Research institutions and networks

Institutions

University Hospital Hradec Králové

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Adela Tomasova

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/01/2019

Study start date
Planned: 01/02/2019

Date of final study report
Planned: 31/07/2021

Sources of funding

- Other

More details on funding

Internal grant of University Hospital Hradec Kralove-Program to support applied health research

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

Effectiveness study (incl. comparative)

Main study objective:

The aim of this tudy was to test anuric patients by using a non-invasive breath test with 13C mixed triglyceride for subclinical pancreatic insufficiency.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Exocrine pancreatic function test

Additional medical condition(s)

The study involved anuric patients undergoing chronic renal replacement therapy. The study focused primarily on the relations between serum indoxyl sulfate concentration and pancreatic exocrine function. This was tested by using a non-invasive breath test.

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

Renal impaired

Estimated number of subjects

27

Study design details

Data analysis plan

All statistical analyses were performed using the SigmaStat software version 3.1 (Systat Software Inc. US). The obtained data are presented as median

(interquartile range) or as mean ± standard deviation. The statistical difference between the groups was tested using a Mann-Whitney rank-sum test and $p \leq 0.05$ was considered statistically significant. The correlation of the parameters was tested using Pearson's correlation coefficient.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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