Intestinal Permeability during Respiratory insufficiency in patients with acute exacerbation of COPD

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The primary objective of the present study is to investigate if the intestinal permeability is increased in patients with an acute COPD exacerbation. To investigate this objective, the following research question have been formulated:- Is intestinal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON38847

Source
ToetsingOnline

Brief title
InPResCO

Condition

- Gastrointestinal conditions NEC
- Respiratory disorders NEC

Synonym
chronic bronchitis, Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, Exacerbation, Intestinal permeability, respiratory insufficiency

Outcome measures

Primary outcome

Main study parameters: intestinal damage and permeability, which will be analysed by several markers in urine and plasma.

- Multi-sugar permeability test

The sugar mixture contains lactulose, sucralose, rhamnose and erythritol. Lactulose and rhamnose are often used as a marker for small intestinal permeability since they are degraded by the bacterial flora in the colon. Sucralose and erythritol can be used as a marker for whole gut permeability since they resist colonic bacterial fermentation. In combination with the lactulose/rhamnose data they provide an insight in colon permeability.

- Determination of intestinal cell damage

Intestinal fatty acid-binding protein (IFABP) is a small cytosolic protein present in absorptive epithelial cells, and is expressed in all parts of the intestine (small intestine and colon, but with the highest expression in the jejunum). In case of intestinal cell damage, these proteins leak from the cells into the circulation and can be measured in plasma.

- Determination of epithelial tight junction proteins in blood and urine

The loss of tight junction protein claudin 3 in the intestinal epithelium

correlates with the appearance of the proteins into plasma and urine.

Secondary outcome

In venous blood, additional markers will be analysed:

Inflammatory markers

Plasma markers of inflammation will be measured to test a correlation between

systemic inflammatory markers and markers of intestinal permeability.

Study description

Background summary

Acute respiratory failure is frequently present in patients admitted with acute exacerbation of COPD. Hypoxemia often is present in these patients but also in patients admitted with AECOPD. Hypoxia might have multiple detrimental effects of which gastrointestinal permeability has gained interest recently. In patients with chronic heart failure, also known to suffer from hypoxic episodes, increased intestinal permeability was recently shown. Its role in exacerbation COPD with acute respiratory failure is not investigated yet but it is supposed to have negative effects on morbidity and clinical course. We hypothesize that COPD leads to an increased intestinal permeability by local oxygen deficit. It could be possible that this has a negative effect on the clinical course of acute hospitalized COPD exacerbations with or without respiratory failure.

Study objective

The primary objective of the present study is to investigate if the intestinal permeability is increased in patients with an acute COPD exacerbation. To investigate this objective, the following research question have been formulated:
- Is intestinal permeability index increased in patients admitted for an acute exacerbation of COPD compared with the permeability index in the same patients in stable COPD condition?

Study design

This study will be a observational single-centre study. Until now, no studies

were done investigating the intestinal permeability in COPD patients with an acute exacerbation, so a lot of new information about the intestinal permeability during exacerbations can be gathered by this project. The study will be carried out at MUMC+ and contains COPD patients admitted to the hospital with an acute exacerbation. The study will not interrupt in the standard care of the exacerbation.

The same study procedures will take place in the first 72 hours of the hospital admission and (at least) 28 days after the first test day.

After overnight fast, a sugar solution will be orally ingested, after collection of a baseline blood and urine sample. Until 1h before the intake of the sugar solution, subjects are allowed to drink water ad libitum. Thereafter, subjects are allowed to drink a maximum of 500ml water per hour. An hour after intake of the sugar solution a standard breakfast will be served. All produced urine will be collected during 5h after drinking the sugar mixture.

Intervention

Intake sugarsolution

Study burden and risks

The additional test is ingesting the sugar solution and collecting venous blood and urine. These actions are virtually without any risks. The blood sampling will occur through an insertion of a cannulla into the vein and a bleu spot may occur. For the ingestion of the sugars, virtually no risks are expected. Over consumption of artificial sweeteners can result in pompous feeling, combined with flatulation and accelerated intestinal transit. The amount of the sugars consumed in the present study are however low and no adverse effects are expected.

There is no direct benefit of participating in the study. In general, receiving more insight in the role on the intestine in the systemic manifestation of COPD will enhance our insight in the extra-pulmonary pathology of COPD and the clinical course of de admission in acute exacerbation COPD patients. This will result in a better (pharmacological or nutritional) treatment of the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosis of COPD stages I-IV as defined by the (GOLD)(7);
- At admission the diagnosis AE-COPD as defined by the (GOLD)(7);
- Both male and female, age-range from 40 years;
- Hypoxemia of PaO2 < 8.7kPa at the moment of hospital admission before administration of medicines;
- Presence of other non-gastro-intestinal related and non-renal chronic diseases are allowed in case the clinical status is stable for at least 4 weeks before the study, except cardiovascular disease;

Exclusion criteria

*Participation in any other study involving investigational or marketed products concomitantly or within two weeks prior to entry into the study;
*Any kind of acute gastro-intestinal complaints or active gastro-intestinal disease;
*The presence of decompensated hearth failure, assessed by analyses of plasma pro-BNP levels;
*Use of NSAIDin the past 48 hours before the tests (ibuprofen, naproxen, meloxicam, diclofenac) with the exception of acetylsalicic acid

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2013
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Na goedkeuring registratie in Nederlands trialregister
CCMO	NL45056.068.13