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Intestinal permeability during exercise (IPEX)

Submission date 30/06/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2009	**Overall study status** Completed	
Last Edited 23/10/2020	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The contribution of the intestinal permeability in the systemic inflammation of patients with chronic obstructive pulmonary disease (COPD) during acute exercise: an observational case-control study

Acronym
IPEX

Study objectives
Intestinal permeability increases during an acute exercise load and plays a role in the systemic inflammation in moderate to severe patients with COPD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
No intervention study.

The study design includes three test days. During day 1, intestinal permeability at rest will be measured. When a blood samples is taken and urine is collected, subjects will ingest a sugar solution in the fasted state after which urine will be collected for 5 hours. In blood and urine, markers for intestinal permeability will be measured. Day 2 and 3 , the same study procedure will take place after the performance of an acute exercise load. The exercise will include a submaximal ergomtery test at 50% of their Wmax or an activity of daily living (ADL) test. The ADL test exist of a combination of several daily activities:
ADL 1: dressing socks, shoes and a coat
ADL 2: fold up 8 towels and put them in the laundry basket

ADL 3: put 6 cans (all 400 g) in a shopping basket
ADL 4: washing 4 plates, 4 cups and 4 saucers and put them in a plate rack
ADL 5: for 4 minutes sweeping plastic blocks with a broom

The mobile Oxycon will measure the ventilated effort (VO2 and ventilation [VE]) in order to calculate the metabolic response of the activities.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Markers for intestinal permeability:

In plasma and collected in the post-absorptive state or immediately after exercise:
1. Intestinal fatty acid binding protein (IFABP);
2. Ileal lipid-binding protein (ILBP);
3. Claudine

In urine, 5 hours after ingestion of the sugar solution:
4. Urinary concentration of various sugars

Secondary outcome measures
1. Markers of systemic inflammation in plasma collected in the post-absorptive state
2. Markers of respiratory permeability (surfactant D) in plasma collected in the post-absorptive state

Overall study start date
01/10/2009

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Diagnosis of COPD Global Initiative for chronic Obstructive Lung Disease (GOLD) stage II or III according to the American Thoracic Society (ATS) GOLD guidelines (forced expiratory volume in one second [FEV1] between 30% and 80% predicted and FEV1/forced vital capacity [FVC] less than 70%, and less than 10% predicted improvement in FEV1 after B2-agonist inhalation)
2. Both male and female, age-range from 40 to 75 years
3. No respiratory tract infection or exacerbation of the disease for at least 4 weeks before the study
4. Capable to provide informed consent
5. 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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70 COPD subjects and 35 control subjects

Total final enrolment
32

Key exclusion criteria
1. External oxygen supplementation at rest
2. Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements
3. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study
4. Any kind of gastro-intestinal complaints or gastro-intestinal disease
5. The presence of cardiovascular disease, assessed by analyses of plasma pro-brain natriuretic peptide (pro-BNP) levels
6. Use of non-steroidal anti-inflammatory drugs (NSAIDs) (ibuprofen, acetylsalicic acid, naproxen, meloxicam, diclofenac) or antibiotics or oral corticosteroids at least 4 weeks before the study

Date of first enrolment
01/10/2009

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Center of expertise for chronic organ failure (Ciro) Horn
Horn
Netherlands
6080 AB

Sponsor information

Organisation

Top Institute Pharma (TIPharma) (Netherlands)

Sponsor details
Wassenaarseweg 72
Leiden
Netherlands
2333 AL

Sponsor type
Industry

Website
http://www.tipharma.com/pro1/general/home.asp

ROR
https://ror.org/01qmxzb47

Funder(s)

Funder type
Industry

Funder Name
Top Institute Pharma (TIPharma) (Netherlands)

Alternative Name(s)
TI Pharma

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2014	23/10/2020	Yes	No