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# Intestinal permeability during exercise (IPEX)

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Diagnostic

## 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(s)
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

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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)

### 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

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |