

Intestinal permeability during exercise (IPEX)

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

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

Primary study design

Observational

Study design

Observational case-control study

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 sample 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 ergometry test at 50% of their Wmax or an activity of daily living (ADL) test. The ADL test consists 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, acetylsalicylic 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