Intestinal permeability during exercise (IPEX)

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 ergometry 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

Kev 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 summaryNot 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