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Interactions between posture and breathing in patients with obstructive sleep apnea syndrome and chronic obstructive pulmonary disease

Submission date
16/03/2017

Recruitment status
No longer recruiting

Registration date
24/03/2017

Overall study status
Completed

Last Edited
12/02/2025

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breathing causes the trunk (torso) and ribcage to move. In some cases, this movement can cause unsteadiness and changes in posture and gait (pattern of movement of the limbs while moving). When a person is suffering from a long term respiratory (breathing disorder) this may have an effect on posture and gait (way of walking). Obstructive sleep apnoea syndrome (OSAS) is a common condition in which the upper airways (wind pipe) collapse repeatedly during sleep, stopping the flow of air into the lungs. This prevents the sufferer from being able to breathe properly while they are asleep, causing excessive sleepiness throughout their waking hours. Chronic obstructive pulmonary disease (COPD) is a condition which affects the lungs and is often caused by smoking. It is characterised by breathlessness, cough and excess mucus production. The aim of this study is to look analyse any possible problems with posture in patients suffering from OSAS or COPD.

Who can participate?
Patients with OSAS or COPD.

What does the study involve?
All participants attend, at least, three study visits. The first involves measuring lung volume by blowing into a machine called a spirometer and takes around two hours. The second visit takes around one hour for COPD patients and one hour and thirthy minutes for OSAS patients and involves completing questionnaires about sleep quality and mood and well as undergoing a physical examination. At the third visit, participants have 78 reflective markers attached to their whole body so that their motion can be monitored to assess their posture, and complete different breathing and cognitive patterns each in a standing position and then a sitting position. Participants also take part in a walking test to measure their gait (way of walking) speed during a real walking test and an imaginary walking test. The second part consists of the posture analysis which is measured by taking a series of pictures taken using low dose x-rays while they are breathing calmly, after taking a deep breath and after breathing out fully in both

sitting and standing positions. OSAS patients are also able to attend two optional visits. At the first, at least two months after the third visit, in which the breathing tests from the third study visit are repeated. At the second, at least six months after the third visit, all of the measurements taken on the third visit are repeated.

What are the possible benefits and risks of participating?
There are no direct benefits and no significant risks involved with participating.

Where is the study run from?
1. Laboratoire de biomécanique humaine Georges charpak Arts et Métiers ParisTech (France)
2. Hôpital Pitié-Salpêtrière (France)

When is the study starting and how long is it expected to run for?
November 2016 to November 2019

Who is funding the study?
National School of Arts and Trades (France)

Who is the main contact?
Dr Valeria Attali
valerie.attali@aphp.fr

Contact information

Type(s)
Public

Contact name
Dr Valérie Attali

Contact details
Pitié-Salpêtrière Hospital
47-83 Boulevard de l'Hôpital
Paris
France
75013

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ADOREPS_2017_P08

Study information

Scientific Title
Study of interactions between posture, locomotion and breathing in patients with obstructive sleep apnoea syndrome (OSAS) and chronic obstructive pulmonary disease (COPD)

Acronym
RespiMeca2

Study objectives
1. In patients with obstructive sleep apnoea syndrome (OSAS), the postural dysfunction is centrally mediated
2. In patients with chronic obstructive pulmonary disease (COPD), the postural dysfunction is multi-factor (linked to the thoracic distension, linked to an abnormal ventilation with dyspnea and centrally mediated)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité de Protection des Personnes Ouest V, 28/06/2017, ref: 17/018-2 and 2017-A00721-52

Study design
Single-centre non-randomised controlled study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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
1. Obstructive sleep apnoea syndrome (OSAS)
2. Chronic obstructive pulmonary disease (COPD)

Interventions
Participants attend a total of five study visits. At the first study visit, after provision of informed consent, participants complete a range of spirometry tests. The visit lasts for a total of around two hours. At the second visit, participants complete a questionnaire about quality of sleep and their mood (anxiety, depression). They additionally undergo a cognitive check-up and an

osteopathic examination. The visit takes around one hour for patients with COPD, and one and a half hours for OSAS patients, who also undergo a voice and prosody test with examination of face motricity which takes around thirty minutes.

If possible, OSAS patients stop their OSAS treatment (mandibular orthosis or CPAP) for 10 days before the third visit. On the third study visit, participants undergo a range of posture measurements using a force platform on the floor and motion capture. This involves having 78 reflective markers affixed to the body, including 35 on the thorax and the abdomen, so that motion capture can be undertaken using an optoelectronic VICON system to assess postural stability. Participants are instructed to perform different breathing and cognitive patterns each in standing position followed by sitting position. This process takes one hour.

The breathing patterns are:
1. Quiet breathing with open eyes and mouth for one minute
2. Quiet breathing with closed eyes and open mouth for one minute
3. Quiet breathing with eyes open and closed mouth for one minute
4. Quiet breathing with eyes and mouth closed for one minute
5. Sniff breathing during 30 seconds
6. Apnea at the CRF (after a normal expiration), VR (after a full expiration) and CPT (after a full inspiration)
7. Deep breathing for 30 seconds

The cognitive patterns are :
1.Quiet breathing and remember 5 two-digit multiplications for one minute and tell the result when the minute is finished
2.Quiet breathing and remember 8 words for one minute and tell them when the minute is finished

Gait velocity is measured using the stand up and go test. This involves participants sitting on a stool before being instructed to stand up and walk three meters before returning to the stool. This test takes approximately 10 minutes.

Gait velocity is measured using the stand up and go test. This involves participants sitting on a chair before being instructed to stand up and walk three meters before returning to the chair. This test takes approximately 10 minutes. Following this, dynamic axis is assessed by measuring angulations of posture using the EOS® system. For patients with COPD or patients with OSAS without any treatment or treated by CPAP, three pairs of images will be done in sitting position (during calm breathing, after a full inspiration and after a full expiration) , and three in standing position in the same conditions. For patients with OSAS treated by mandibular protrusion orthosis, four pairs of images will be done in standing position (during calm breathing, after a full inspiration and after a full expiration and the last during calm breathing with the orthosis), and two in sitting position (during calm breathing with and without orthosis). This process takes approximately 45 minutes.

Participants with OSAS are then given the option to return for a fourth study visit at least two months after the third study visit at which only the breathing and cognitive patterns are repeated , and then a fifth study visit at least 6 months after the third visit at which all the tests undertaken on the third visit are repeated.

Intervention Type
Other

Primary outcome measure
Postural stability is assessed using a force platform and motion capture taken by an optoelectronic VICON system on study visit 3 (as well as 4 and 5 for OSAS patients)

Secondary outcome measures
1. Angulations in posture is measured using the EOS® system on study visit 3 (as well as 4 and 5 for OSAS patients)
2. Gait velocity is measured using the stand up and go test on study visit 3 (as well as 4 and 5 for OSAS patients)

Overall study start date
02/11/2016

Completion date
02/11/2019

Eligibility

Key inclusion criteria
1. Moderate to severe OSAS diagnosed thanks to polysomnography
2. COPD diagnosed thanks to the symptoms and functionnal respiratory analysis
3. Aged 18 years and over
4. Should understand the informations and sign the consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 patients with OSAS and 30 patients with COPD

Key exclusion criteria
1. Pregnant or nursing women (female patients)
2. Under judicial protection
3. If the subject realises an other study wich prohibits him to be involved in another study
4. Aged under 18 years

Date of first enrolment
12/07/2017

Date of final enrolment
02/11/2019

Locations

Countries of recruitment
France

Study participating centre
Laboratoire de biomécanique humaine Georges charpak Arts et Métiers ParisTech
155 boulevard de l'hôpital
Paris
France
75013

Study participating centre
Hôpital Pitié-Salpêtrière
47-83 boulevard de l'hôpital
Paris
France
75013

Sponsor information

Organisation
Association pour le Développement et l'Organisation de la Recherche en Pneumologie et sur le Sommeil (ADOREPS)

Sponsor details
Hôpital Pitié Salpêtrière
47-83, Boulevard de l'Hôpital
Paris Cedex 13
France
75651

Sponsor type
Other

Funder(s)

Funder type
University/education

Funder Name
National School of Arts and Trades (Ecole Nationale Supérieure d'Arts et Métiers)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
02/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Valérie Attali (valerie.attali@aphp.fr)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/02/2020	12/02/2025	Yes	No