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The relationship between the shape of face and size of the airway in subjects with obstructive sleep apnoea syndrome

Submission date 27/07/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 19/02/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/01/2019	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea- hypopnoea syndrome (OSAHS) is a common condition in which the upper airways (wind pipe) collapse repeatedly during sleep, completely (apnoea) or partially (hypoapnoea) blocking 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. Many studies have shown that people who are obese have a higher risk of developing it and that the incidence of OSAHS is increasing with the rise in obesity. Although there is a strong relationship with obesity however, this does not mean that all obese people have OSAHS and normal weight people do not. Previous studies have tried to use facial characteristics such as face shape (phenotype) to predict the occurrence of OSAHS, however this screening technique is widely debated. The aim of this study is to find out whether the visual characteristics of the face and neck (phenotyping) can be used in order to develop a new pre-screening tool for people suffering from OSAHS.

Who can participate?
Caucasian men aged between 45 and 65, either normal weight or obese who either have OSAHS or show no signs of it.

What does the study involve?
All participants then attend two study visits. At the first study visit, all participants complete a number of questionnaires as well as having their weight and height measured and medical history taken. Then then have a simple physical examination in order to assess their neck and facial characteristics. At the second study visit, participants all participants have a cone beam computed tomography scan (a high resolution type of x-ray) and have a 3D analysis of their facial characteristics. At the end of the second visit, the characteristics of all participants are compared between the those with OSAHS and those without.

What are the possible benefits and risks of participating?
There are no direct benefits to participants; however the participants with OSAHS may be able to gain a better understanding of the underlying causes of their condition. Participants are

exposed to a very small amount of radiation during the scanning procedures, however this is not considered to be harmful.

Where is the study run from?
Bart's & The London Dental Institute (UK)

When is the study starting and how long is it expected to run for?
November 2015 to November 2017

Who is funding the study?
Queen Mary University of London (UK)

Who is the main contact?
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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 relationship between facio-cervical phenotyping and upper airway morphology in obstructive sleep apnoea-hypopnoea syndrome: A 3-dimensional approach

Study objectives
Null hypotheses:
1. Obstructive sleep apnoea-hypopnoea syndrome (OSAHS) subjects cannot be identified from their facio-cervical form (phenotype)
2. There is no correlation between the soft tissue facial morphology and underlying skeletal morphology
3. There is no correlation between the surface facial morphology and the upper airway of OSAHS subjects
4. It is not possible to identify or create a facio-cervical prediction tool (marker) for OSAHS subjects

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee, 17/05/2016, ref: 16/LO/0554

Study design
Single-centre case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

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
Obstructive sleep apnoea-hypopnoea syndrome (OSAHS)

Interventions
Interventions as of 02/06/2016:
In the first study visit, both obstructive sleep apnoea-hypopnoea syndrome (OSAHS) diagnosed participants and suspected non-OSAHS participants will complete the consent form and undergo the baseline assessment including simple clinical examination to determine the number of teeth and examine the back of the throat (Mallampati airway classification (MAC)) and anthropometric measurements to measure the body mass index (BMI) and neck circumference (NC). Then the suspected non-OSAHS (healthy) subjects will be asked to complete a series of questions and

undergo an overnight sleep test (at home). The sleep test and questions will help to identify if they suffer from obstructive sleep apnoea.

At the second study visit, all participant will undergo cone-beam computed tomography (CBCT) first then three-dimensional (3D) stereophotogrammetry scan.

For whole participation, the average time taken for each participant is around 1 hour ± 5 minutes (over the two visits).

Original interventions:
Both obstructive sleep apnoea-hypopnoea syndrome (OSAHS) diagnosed participants and healthy participants added a study visit which involves the completion of a consent form, history & clinical examination, weight and height assessment and pre-screening questionnaires. All participants will undergo a simple clinical examination (to determine the number of their teeth, body mass index (BMI), neck circumference (NC), and Mallampati airway classification (MAC). In addition, the control subjects (non-OSAHS), will complete pre-screening questionnaires (Epworth sleepiness scale (ESS), sleep apnoea clinical score (SACS) and sleep partner questionnaire (SPQ)) to exclude OSAHS.

At a second visit, all participants undergo imaging procedures. OSAHS participants will undergo cone-beam computed tomography (CBCT) and then three-dimensional (3D) stereophotogrammetry scan and non-OSAHS participants will undergo a lateral cephalometric radiograph, followed by a 3D stereophotogrammetry scan.

For whole participation, the average time taken for each participant is around 1 hour ± 5 minutes (over the two visits).

Intervention Type
Mixed

Primary outcome measure
Facio-cervical morphology (phenotype)measured using image analysis software for stereophotogrammetry scan, lateral cephalometric radiograph, and cone-beam computed tomography (CBCT) at the second visit after baseline assessment.

Secondary outcome measures
1. The correlation between the surface and skeletal facio-cervical morphology and upper airway dimensions using correlation analysis after the second visit
2. Potentially identifying a facio-cervical marker for OSAHS subjects using multiple regression analysis after the second visit

Overall study start date
05/12/2014

Completion date
01/10/2018

Eligibility

Key inclusion criteria

1. 40 to 65 years old males
2. Clinically normal weight (BMI <25 Kg/m2) or obese (BMI >30Kg/m2)
3. Caucasian
4. Confirmed diagnosis of OSAHS in the study group and no clinically demonstrable OSAHS in control group
5. Dentate
6. The skin over the face and neck must be free of significant hair.

Participant type(s)
Mixed

Age group
Adult

Sex
Male

Target number of participants
132 dentate Caucasian male adults meeting selection criteria

Key exclusion criteria
1. Edentulous subjects or the absence of 8 or more teeth in each dental arch
2. Facial neuromuscular disorders, craniofacial deformity or history of craniofacial surgery
3. Overweight subjects (BMI between 25 and 30 Kg/m2)

Date of first enrolment
01/04/2016

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and the London School of Medicine & Dentistry
Bart's & The London Dental Institute
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Queen Mary University of London

Results and Publications

Publication and dissemination plan
The results of the study will be published in peer-reviewed medical and dental journals. In addition, they will be presented at sleep conferences. A summary of the key findings will be sent to all participants.

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No