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The association between various diagnostic measurements and lung function

Submission date 14/02/2020	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/06/2020	**Overall study status** Ongoing	
Last Edited 04/04/2025	**Condition category** Respiratory	

Plain English summary of protocol
Background and study aims
The main function of lungs is gas exchange through gas transport. Due to the complexity of the lung structure, gas transport can only be optimized to a certain extent and is easily affected by changes in the small airways.
The overall aim of this study is to prospectively associate various pulmonary function tests with clinical, laboratory, histological and radiological characteristics.

Who can participate?
People aged 18 years or above.

What does the study involve?
Participants will undergo several lung function tests during a single visit.

What are the possible benefits and risks of participating?
None.

Where is the study run from?
University Hospital Basel, Clinic for Respiratory Medicine and Pulmonary Cell Research (Switzerland)

When is the study starting and how long is it expected to run for?
April 2019 to April 2028

Who is funding the study?
University Hospital Basel (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PFT_Prosp_Amendment 01

Study information

Scientific Title
Pulmonary function test association with clinical, laboratory, histological and radiological characteristics – a prospective study

Acronym
N2

Study objectives
The overall aim of this study is to prospectively associate various pulmonary function tests with clinical, laboratory, histological and radiological characteristics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2019, EKNZ (Ethics Committee Northern and Central Switzerland, Hebelstrasse 53, Basel 4056, Switzerland; +41 612681350; eknz@bs.ch), ref : 2018-0286, Amendment approved 27/11/2019

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory diseases

Interventions
Non-invasive measurements specific to the project and performed in all participants, include:
N2 washout (single and multiple breath):
Single breath - the measurements are carried out with the patient sitting upright and breathing normally. The test subjects breathe through a mouthpiece with a nose clamp that is attached to the measuring device. A bacteria filter is installed upstream of the measuring device. The filter, mouthpiece and nose clip are replaced after each patient. The measurement device is based on an ultrasonic flow head, the Exhalyzer® (Eco Medics AG, Dürnten, Switzerland), connected to a bypass element that provides constant air intake. The gas used as part of the study (100% O2,

DTG) is supplied to the patient via this bypass element. During the measurement procedure, the accurate recording of the flow volume curve and the gas signals (O2, CO2 and the derived N2, molar mass signal) enable good online monitoring of the measurement quality. Any changes to the patient's breathing pattern, hyperventilation or leaks are identified immediately and the measurement procedure is terminated.
Multiple breath - for N2 MBW, the supply of 100% O2 flushes out the nitrogen in the lungs. The test ends when < 2% end-expiratory N2 (1/40 of the starting concentration) is reached over three consecutive breaths. For the evaluation, all signals are aligned in terms of time, and the respiratory flows and derived breathing volumes are corrected for body temperature, ambient pressure and humidity. To calculate the functional residual capacity (FRC), the ratio (net volume of expirated tracer gas) / [(end-expiratory N2 concentration at start of washout measurement) – (end-expiratory N2 concentration at end of the washout measurement)] is calculated. Over the course of the three requisite measurements per patient, the FRC must not deviate by more than 20%; otherwise, the measurement must be rejected. The LCI is calculated via FRC as the ratio of the cumulative expirated volume.
Forced oscillation technique (FOT) - the sound waves, generated with the help of a loudspeaker are transmitted into the lungs of the subject. These sound waves, which are essentially pressure waves, cause changes in the pressure and this change in pressure drives changes in airflow. By measuring the magnitude of change in the pressure and flow, one can determine the mechanical properties of the lung. Waves of lower frequencies travel deep into the lungs till and into the alveoli and are reflected back while those of higher frequencies are reflected from the larger airways. Thus, the parameters calculated at different frequencies give measures of different regions in the lungs.
Aeonose – Measured data consists of an individual breath-print of volatile organic compounds. Patients breathe into the portable Aeonose for five minutes. The system learns from each data entered and is updating consistently. The device is CE-certified and therefore there is no risk in using it for our patients.
Sleepiz One – A contactless, non-invasive device that measures vital parameters while patient is at rest. It is a radar-based sensor that does not pose any risks. The electromagnetic emission is around 100 times lower than that of a typical mobile phone.
Along with the study-specific interventions, routine interventions such as body plethysmography are also performed.

Intervention Type
Other

Primary outcome measure
Measured at a single time point:
1. LCI measured using the multiple-breath nitrogen washout (N2-MBW)
2. Phase III slope (SIII) measured using the single-breath nitrogen washout (N2-SBW) and single-breath double tracer gas washout (DTG-SBW)

Secondary outcome measures
Measured at a single time point:
1. Scond, Sacin, area under the curve of DTG-SBW measured using the multiple-breath nitrogen washout (N2-MBW)
2. Bronchoprovocation test outcomes such as PD20 and PD40
3. Volatile organic compounds in the breath measured using Aeonose
4. Sleepiz One measurements (breathing, heart rate, movement during sleep)
5. Known clinical, laboratory, histological and radiological characteristics measured using patient records

Overall study start date
01/04/2019

Completion date
30/04/2028

Eligibility

Key inclusion criteria
1. Older than 18 years
2. Capable to perform an acceptable spirometry
3. Able to answer questionnaires
4. With or without respiratory symptoms
5. With or without diagnosed respiratory disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2019

Date of final enrolment
30/04/2028

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Clinic for Respiratory Medicine and Pulmonary Cell Research
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.unispital-basel.ch/

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel

Results and Publications

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

Intention to publish date
30/04/2029

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v5	27/11/2019	03/07/2020	No	No
Results article		03/04/2025	04/04/2025	Yes	No