

The association between various diagnostic measurements and lung function

Submission date 14/02/2020	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/06/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/04/2025	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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?

Prof. Daiana Stolz
daiana.stolz@usb.ch

Contact information

Type(s)

Scientific

Contact name

Prof Daiana Stolz

ORCID ID

<http://orcid.org/0000-0003-0099-882X>

Contact details

University Hospital of Basel
Clinic for Respiratory Medicine and Pulmonary Cell Research
Petersgraben 4
Basel
Switzerland
4031
+41 612654422
daiana.stolz@usb.ch

Type(s)

Scientific

Contact name

Dr Vivian Suarez Domenech

Contact details

Universitätsspital Basel
Pneumologie
Petersgraben 4
Basel
Switzerland
4031
+41 61 328 69 17
vivian.suarezdomenech@usb.ch

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 expired 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 expired 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 (S_{III}) 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
Petersgraben 4

Basel
Switzerland
4031

Sponsor information

Organisation

University Hospital of Basel

Sponsor details

Clinic for Respiratory Medicine and Pulmonary Cell Research
Petersgraben 4
Basel
Switzerland
4031
+41 612654422
daiana.stolz@usb.ch

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