Document date: February 1, 2022

Patient Consent

Measurement of breathing parameters of asthma and COPD patients with different degrees of disease severity for the computer simulation of lung deposition of aerosol drugs

Study ID: TBEP-2021.05/001
Version: 2021 V2
Location of the measurement:
Study supervisor: **Dr. Gabriella Gálffy PhD**, director, pulmonologist

Informing doctor's name:
……..
Patient study ID (centre ID/patient no): ……...

Undersigned, ……[1] I have was provided oral information and instructions on the above study and I have carefully read the attached Patient Information. I had the possibility to discuss the above study with the examining doctor. I was given the possibility to ask questions in connection with the study.
I agree to participate in this study as a volunteer. I have understood that I can withdraw my consent at any time without reasoning and that the withdrawal has no effect on my therapy.
Hereby I consent that my personal data is used according to those stated in the Patient Information.
I declare that I have received one copy of the Patient Consent and Patient information.

□ yes □ no

……	……..
Patient's signature	Date, handwritten by the Patient
……	……
Informing Doctor's signature	Date, handwritten by the Doctor

[1] Patient's name with capital letters

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Patient Information

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Dear Patient,

Hereby we are inviting you to participate in our observational clinical study. Before deciding on your participation it is important to get familiarized with the scope of the study, how the acquired data will be used, what are the possible advantages and risks. Please read carefully the information below. In the case you are presently participating in another study, please let us know.

Background and scope of the study

Our aim is to study the deposition of aerosol drugs emitted by different dry powder inhalers in the airways of asthmatic and COPD (chronic obstructive pulmonary disease) patients. This is the drug dose which is inhaled by the patient and remains in the lung to exert its effect. This dose depends on the breathing mode of the patient. Since lung capacity and the force an individual can inhale through an inhaler is patient specific, it is necessary to measure the inspiratory flow and the inhaled volume also in your case. This is similar to the spirometric measurements that your doctor may have already completed, but this time you will inhale through empty inhalers.

The strength of your inhalation through the inhaler depends on the inhaler, but also on your disease status and it can change over the time. It is a useful information to assess the amount of drug reaching your lung corresponding to your breathing pattern. This is not measured routinely, but it will be measured in the case you participate in our study.

The data that we gain may help us to optimize the inhalation drug therapy in the future.

The scope of the study is to measure your breathing parameters and apply them to assess the drug dose reaching your lungs. The study is underpinned by the findings of several research papers and previous studies on patients suffering from lung diseases.

Is it compulsory to participate?

Your participation is not compulsory. It is only upon your own decision whether you participate or not. Your absence will not induce any disadvantage. If you decide to participate, then you must sign the current Patient Information and the Patient Consent. Your consent must be volunteer and free of any external influence. You can withdraw your participation any time in the future in either written or oral form.

What are the circumstances of your participation in the study?

Similarly to a normal examination, your doctor registers your data, but this time the data will be registered also on a sheet that belongs to the study.
The doctor will document your gender, weight and height (later, the last two will result in a body mass index value). Your underlying disease will also be noted, as well as the date of first diagnosis and its status (controlled or exacerbation). The doctor will control your comorbidities in the documentation, but will also ask you about possible new diseases. The doctor will document whether you had COVID19. Your smoking habits will also be documented. Next, the status of your disease (asthma or COPD) will be evaluated based on your symptoms from the past year and your actual symptoms (especially in the case of asthma by the help of an asthma control test). Your actual treatment and the need for reliever will be (re)evaluated. You will be asked about eventual unexpected event or side effect in connection with your treatment. If you are suffering from COPD, the doctor will perform an assessment test to clarify your status.
You will be instructed on the use of the inhaler(s) and the effectiveness of the patient education will be recorded.
In the case of complaint, you will undergo three correctly carried out spirometry tests and the best result will be documented. In the frame of the current study you will be asked to inhale through empty inhalers (with no drug substance). Your breathing data through the inhaler will be automatically recorded by a hand-held spirometer connected to the inhaler.

What are the possible risks, side-effects or inconveniences related to the study?
Since the examination is similar to a normal examination any increase in the risk is not expected. You will not inhale and drug during this session, thus the risks associated with drug use are excluded.

What are the possible advantages of the participation?
Direct, immediate advantages are not expected. However, based on the measured data the drug dose in your lungs will be evaluated by computer simulations. Based on the results, combined with the results of our participants some conclusions will be drawn which may help a more appropriate inhaler device selection and a more efficient inhalation therapy in the future.

How my personal data will be handled?
By signing the Patient Consent document you agree that the doctor collects and uses the following data:

- birth date
- gender
- data characterizing your health status
- breathing parameter values measured when inhaling through inhalers.

Your anonymized data will be used for the purpose of the study complying with the data protection rules. Your data will not be provided to third parties, except for research purpose, anonymized and respecting strict rules stated in the study protocol.

How can I get further information or help in connection with my participation in the study?

Should you have any further question, do not hesitate to ask the study supervisor mentioned in the header of Patient Consent and Patient Information documents. You can also contact your patients' rights representative (Meglécznné Ocsenás Mária, e-mail: maria@ocsenas@ijb.emmi.gov.hu, phone: 06 20 489 658.

……	……..
Patient's signature	Date, handwritten by the Patient
……	……
Informing Doctor's signature	Date, handwritten by the Doctor