Comparative efficacy of once-daily LAMA/LABA combinations versus tiotropium on constant-work-rate cycle endurance in COPD: randomised crossover study (COMPETE)

NCT:xxxxxxxxxxx

14.02.2026

Information for patients

Please give your consent for your blood to be used in a study entitled: Comparative efficacy of once-daily LAMA/LABA combinations versus tiotropium on constant-work-rate cycle endurance in COPD: study protocol for a randomised crossover study (COMPETE)

The aim of the study is to compare the effect of commercially available combination bronchodilator preparations (known as LABA/uLAMA) with tiotropium (LAMA) on physical performance and pharmacoeconomic efficiency in patients with chronic obstructive pulmonary disease.

The planned study will be conducted on a group of approximately 100 COPD patients treated at the 2nd Department of Pulmonary Diseases and Tuberculosis of the Medical University of Białystok and at the Pulmonary Diseases Clinic of the University Clinical Hospital in Białystok in a prospective open-label observational study, with random assignment of patients to study groups in a cross-over (alternate selection of study participants to subsequent groups with study drugs), in a head-to-head formula (direct comparison of drugs on the endpoints relative to each other and a common comparator). The study group will consist of patients qualified for COPD treatment with uLAMA+LABA. The control group will consist of individuals treated for COPD with tiotropium.

Treatment will be carried out with four commercially available COPD drugs (Anoro Elipta, Spiriva, Spiolto Respimat, Ultibro). The duration of treatment with each drug will be 28 days, followed by a 7-day break (the so-called wash-out period), after which you will be randomly assigned to a new study group with the next drug. The procedure will be repeated so that you have the opportunity to be treated with each of the drugs.

During the qualification process and after each 28-day treatment period, the following tests will be performed:

1. General examinations:
    - Blood pressure measurement
    - Anthropometric measurements:
    - Height, body weight, BMI
    - St. George's Respiratory Questionnaire (SGRQ) o COPD Assessment Test (CAT)
    - mMRC scale
    - BODE scale
2. Physical performance tests:
    - Spirometry
    - CPET performance test on a bicycle ergometer
3. Laboratory tests:
    - Myostatin level

The tests will be carried out at the 2nd Clinic of Lung Diseases and Tuberculosis of the Medical University of Białystok and are part of the routine assessment of each COPD patient. In addition, an exercise test on a bicycle ergometer will be performed. This test allows for the assessment of physical fitness and the possibility of improving respiratory efficiency as a result of the treatment used. A properly performed exercise test involves putting on a mask connected to a measuring device and performing a set amount of physical exercise on a stationary bicycle. Before the test, a suitable mask must be selected to ensure a good seal during the test. The test is conducted until you refuse to continue. When you give the agreed signal to end or stop the exercise, the load from the device is reduced to the initial value and the device records 3 minutes of rest. The medications used during the test will be provided to you free of charge as part of the study.

Białystok, ...

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Investigator's signature

Appendix No. 1 to the Personal Data Protection Policy in Research at the Medical University of Białystok

Information obligation towards participants in research conducted at the Medical University of Białystok

Pursuant to Article 13 of the General Data Protection Regulation of April 27, 2016 (Official Journal of the European Union L 119 of May 4, 2016), I hereby inform you that:

1) The Personal Data Controller is the Medical University of Białystok with its

registered office at ul. Kilińskiego 1, 15-089 Białystok, represented by the Rector,

2) Contact details for the Data Protection Officer at the Medical University of Białystok,

email address: iod@umb.edu.pl,

3) Your personal data may only be disclosed to persons authorized by the controller to process personal data, to processors under a processing agreement, and to other entities authorized under the law,

4) Your personal data will be stored only for the period necessary to carry out the research,

5) You have the right to access your data, the right to rectify, delete, restrict processing, the right to transfer data, the right to object,

6) You have the right to withdraw your consent to the processing of personal data at any time.

7) You have the right to lodge a complaint with the President of the Personal Data Protection Office if there are grounds to believe that your personal data is being processed by the controller in violation of the General Data Protection Regulation of April 27, 2016.

8) providing personal data is voluntary, but necessary for the study to be carried out

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Date and legible signature of the study participant

CONSENT FORM

Project title: "Comparative efficacy of once-daily LAMA/LABA combinations versus tiotropium on constant-work-rate cycle endurance in COPD: study protocol for a randomised crossover study (COMPETE)"

Patient's first and last name: .....

I declare that, having read the information regarding the purpose and nature of the study and having received answers to all my questions, I give my full, informed, and voluntary consent to participate in the proposed study.

I also consent to the publication of the results obtained in scientific journal(s), subject to the anonymity of my personal data, in accordance with the Personal Data Protection Act of May 10, 2018.

I am aware of my right to withdraw from participation in the study at any stage, without giving a reason. I also know that exercising this right will not affect

the further course of my treatment. I have received the Patient Information Form and the Informed Consent Form for participation in the study.

Date:.....

Patient's signature .....

First and last name and signature of the person receiving the consent.

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Date. .....