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Assessment of physical capacity of patients diagnosed with bronchial asthma

Submission date
11/07/2023

Recruitment status
No longer recruiting

Registration date
03/08/2023

Overall study status
Completed

Last Edited
03/08/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma has a significant impact on the functioning of the patient in society, their physical activity and sports. Typical symptoms of asthma include worsening respiratory symptoms after intense exercise. At the same time, the degree of physical activity is the basic parameter for assessing the degree of disease control. Control of this disease is achieved through appropriate pharmacological treatment and physiotherapeutic activities. The aim of the study is to assess physical capacity in patients diagnosed with bronchial asthma.

Who can participate?
Adult patients aged over 18 years old with bronchial asthma

What does the study involve?
Patients from the research group were qualified for the study on the basis of the results of spirometry tests and bronchial asthma criteria by physicians specializing in allergology and pulmonology. Each subject was informed about the method of conducting the research, the aims of the study and the methods used, and gave written consent.

The protocol of each study includes an interview, instruction on the purpose of the measurements and study procedures. For patients from the research group, the visit protocol consists of a four-part assessment protocol that will look at the subjective feeling of exertion, the severity of dyspnea, quality of life, physical capacity and the degree of physical activity.

The control group patient protocol includes the assessment of the subjective feeling of exertion, the severity of dyspnea, physical capacity and the degree of physical activity.

What are the possible benefits and risks of participating?
Each of the patients who qualify for the study may withdraw from participation at any time. The results of the research will be used to participate in the discussion on the assessment of efficiency, quality of life and the latest forms of therapy used in patients diagnosed with bronchial asthma. There are few risks to participation and for the safety of patients, before and after the six-minute walking test, blood pressure and heart rate, dyspnoea and fatigue will be measured.

Where is the study run from?
Wrocław Medical University (Poland)

When is the study starting and how long is it expected to run for?
November 2018 to February 2019

Who is funding the study?
Wroclaw Medical University (Poland) - SUBZ.E060.23.037

Who is the main contact?
Miss Weronika Bajer, weronika.bajer@umw.edu.pl (Poland)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Assessment of phySical capacity in patienTs diagnosed with moderate and severe broncHial Asthma (study group) using a 6-minute walk test, the St. George and the International Physical Capacity Questionnaire (IPAQ) - study with a control group

Acronym
ASTHMA

Study objectives
The aim of the study is to assess physical capacity and quality of life in patients diagnosed with bronchial asthma and to compare them with patients without cardiopulmonary diseases.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/10/2018, Institutional Review Board at Wroclaw Medical University (ul. J. Mikulicza-Radeckiego 4a, Wrocław, 50-367, Poland; +48 (0)71 784 10 14; bioetyka@umw.edu.pl), ref: KB-568/2018

Study design
Cross-sectional multicentre cohort study

Primary study design
Observational

Secondary study design

Cross sectional study

Study setting(s)
Hospital, Other

Study type(s)
Other, Quality of life

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

Health condition(s) or problem(s) studied
Bronchial asthma

Interventions
The study will be carried out in two outpatient clinics. Patients diagnosed with bronchial asthma will be examined in the pulmonology clinic and included based on the outcome of spirometric tests carried out by pulmonologists and on the basis of anamnesis, complaints and medical history. Patients without cardiological, pulmonological and orthopedic burdens will be tested as a control group in another clinic.

To determine the physical capacity of patients in both groups, a six-minute walk test and measurement of oxygen saturation and blood pressure will be performed. Saturation and blood pressure levels were measured twice, before and after the walk test. To determine the quality of life, the Saint George's Quality of Life Questionnaire will be undertaken for patients with respiratory diseases after prior written consent from the author of the questionnaire.

The examination of each patient includes instruction on the purpose of the study and its procedures, consent to participate in the study and the possibility of withdrawing from it, a single diagnostic survey and self-observation. The time of observation, assessment and examination of each patient lasted about 1.5 hours. The results of the research were subjected to statistical analysis.

Intervention Type
Other

Primary outcome measure
1 Physical capacity measured using the 6-minute walk test (6MWT) at one timepoint
2. Degree of physical activity measured using the International Physical Activity Questionnaire (IPAQ) at one timepoint
3. Quality of life assessments measured using the St. George's Respiratory Questionnaire at one timepoint

Secondary outcome measures
Secondary outcome measures are assessed before and after 6MWT:
1. Blood pressure measured using a blood pressure monitor
2. Pulse measured using a pulse oximeter
3. Patient perception of exertion measured using Borg's subjective perception of exertion
4. Dyspnoea measured using the MRC Dyspnoea Scale

Overall study start date
30/09/2018

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Diagnosed with bronchial asthma
2. Current spirometry test performed by a doctor
3. Age >18 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
63

Key exclusion criteria
1. Patients with cardiac disease
2. Patients with upper and lower respiratory tract infection in the last 2 weeks
3. Patients with asthma (control group)
3. Patients who do not consent to the research

Date of first enrolment
01/11/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Poland

Study participating centre
EMC Medical Institute
Wejherowska 28/4
Wrocław
Poland
54-239

Study participating centre
Health Care Team in Saint Catherine (Zespol Opieki Zdrowotnej Święty Katarzyna)
Żeromskiego 1
Saint Catherine
Poland
55-010

Sponsor information

Organisation
Wroclaw Medical University

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Sponsor type
University/education

Website
https://www.umw.edu.pl/pl/jednostki/katedra-fizjoterapii

ROR
https://ror.org/01qpw1b93

Funder(s)

Funder type
University/education

Funder Name

Uniwersytet Medyczny im. Piastów Slaskich we Wroclawiu

Alternative Name(s)
Wroclaw Medical University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

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

Intention to publish date
10/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are available from Miss Weronika Bajer (weronika.bajer@umw.edu.pl) upon request. Raw data (taking into account the anonymity of patients) will become available from the end of the study for 5 years. The research results will be passed on to other researchers in order to compare these results with the results of their own research.

IPD sharing plan summary
Available on request