Background:

Nowadays a shift of the paradigm is taking place in the field of chronic respiratory diseases from treatment of diagnostic entities to management of treatable traits [1, 2]. This transition has been preceded by the introduction of the concepts “phenotypes” and “endotypes” [3], which have broken down the ‘asthma-COPD spectrum’ into smaller entities, much better characterizing smaller and smaller groups of patients. **This contemporary trend could best be supported by real life studies encompassing a broad spectrum of patients with airway obstructive symptoms.**

With the vigorous development of new technologies capable of assessing cellular and molecular signatures, the expectations are that personalized and precision medicine will transform the field of obstructive lung diseases. However, in routine clinical practice decision making and follow up of patients is still based on symptoms and lung function measurements. The prospects are that this practice will not change overnight. So far the measurement of biomarkers is associated with sophistication and high costs. In terms of assessment of airway inflammation, it is still eosinophils in blood and sputum and the recently added fractional exhaled nitric oxide (FeNO) that physicians place their judgment on. These deficits are all the more true for regular home monitoring of patients, where telemedicine is confined to answering questions related to symptoms, rescue medication usage and measurement of peak expiratory flow (PEF) and / or some other basic spirometric indices.

Since the beginning of this century a new approach for assessing inflammation has been proposed: measurement of exhaled breath temperature (EBT) [4, 5]. The studies performed in subjects with fixed airway obstruction and longer disease duration have deepened our insight of the nature of EBT and evidence emerged that there might be other determinants of EBT, which need to be considered, like changes in the geometry of the bronchial tree as a result of airway remodeling, and air trapping [6]. Over the span of a decade the work on the practical applicability of the method has resulted in precise, user-friendly and cheap devices meeting the criteria for personalized / precision telemedicine [7-9]. The new device ‘X-halo Home’ is designed for individual daily use, operates through an app on smartphones and tablets, provides the measurement results within less than 10 breaths, draws a chart with the measured values positioned on a floating average of 10 days with calculated green, yellow and green zones based on standard deviations. It also documents information on asthma control, and
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prescribed treatment. The data can be uploaded on a specialized site and transmitted to the treating physician at the discretion of the patients. It has been granted ‘CE (European Conformity) mark’ by the TÜV institute in Munich.

**Our proposed research aims to assess the ability of X-halo Home to differentiate / characterize different airway obstructive states.**

Research question:

- **Will daily measurement of exhaled breath temperature (EBT) under standardized ICS-LABA treatment identify intermediate phenotypes along the asthma – COPD spectrum?**

Research hypothesis:

-> **EBT decreases over the Asthma - COPD spectrum in stable disease proportional to the reduction of the airways vascular bed; however, fluctuations in diseases activity over time will be different between the two extremes (Asthma & COPD) in terms of variability of the daily measurements (similar to peak expiratory flow (PEF)-metry) and during exacerbations; intermediate group(s) of patients may shape up corresponding to intermediate (ACOS) phenotype(s).**

Provisional study design:

=>> A cohort of patients with features of asthma and/or COPD indicated for ICS+LABA treatment will be followed up for 6 months; EBT daily measurements (time series analysis) will serve as dependent variable and will be correlated with symptoms and PEF measurements. Spirometry and blood indices (hematology, hsCRP) will be performed at baseline, 3rd and 6th months.

Budget:

As this is an exploratory proof-of-concept study, no sample size can be calculated. Some 100 patients would suit the purpose to identify trends. Depending on the specifics of the finalized protocol, the budget can be anywhere between 30,000 and 90,000 Euros.

References:

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