FeNO@Home: a proof of concept protocol for home monitoring fractional exhaled nitric oxide in patients with ashtma

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Introduction

BACKGROUND: Fractional exhaled nitric oxide (FENO) is a non invasive method to assess airway inflammation and its levels are associated with worsening of asthma control and exacerbations, while they tend to rapidly reduce when a proper asthma treatment is established. FENO is widely used in the asthma management, but classically during visits at asthma centers, and therefore not able to give a continous monitoring of airway inflammation.

AIM OF THE STUDY: To collect data about the potential benefits, feasibility/usability and compliance of regular FENO measurements at home for both patients and physicians, and to investigate FENO variability (inter- and intra-individual variation, and variations by period) in patients with asthma.

BOSCH

Vivatmo me

World's first and **only** FeNO measuring device for **home use**

The Bosch Vivatmo *me* is intended for quantitative measurement of fractional nitric oxide (FeNO) in human breath.

- Intended to be <u>used at home</u> by patients of 7 years and older as an aid to **monitor airway diseases** (whilst under care of a physician or healthcare expert).
- Measurement procedure based on the recommendations of the European Respiratory Society (**ERS**) and the American Thoracic Society (**ATS**).

Methods

Innovative study design:

- ✓ Pragmatic, observational
- ✓ Multinational, multicentre: 4 sites in DE and IT
- ✓ Goal: N > 100 asthmatics GINA steps 1-5
- ✓ Identification of the patient-specific research question on the potential benefit of FeNO
- ✓ 12 weeks observation period with daily FeNO measurement at home
- ✓ Digital asthma diary via mobile phone app (symptoms, medication, exacerbations, PEF, and pollen forecast)
- ✓ 4 visits / contacts, with individual therapy adjustment as needed

Vivatmo *app* for the gathering and sharing of relevant disease-related data:

- ✓ Individual asthma diary for recording FeNO values (via Bluetooth), peak flow values, medication intake, symptoms and pollen data
- ✓ Monthly PDF-report (patients)
- ✓ CSV-file (professionals)

Expected results

Potential benefits:

- Profound treatment choices for better asthma management:
  - Detection of inflammation profile
  - Observation of treatment response
  - Identification of asthma triggers
  - Detection of exacerbations
- More patient involvement, better adherence and self-management through knowledge gain

As of 2 Aug 2023, **81 patients** have been enrolled in the study at 4 centers. Of these, 52 patients have already completed the study.

22 GINA step 1
38 GINA step 2-3
21 GINA step 4-5
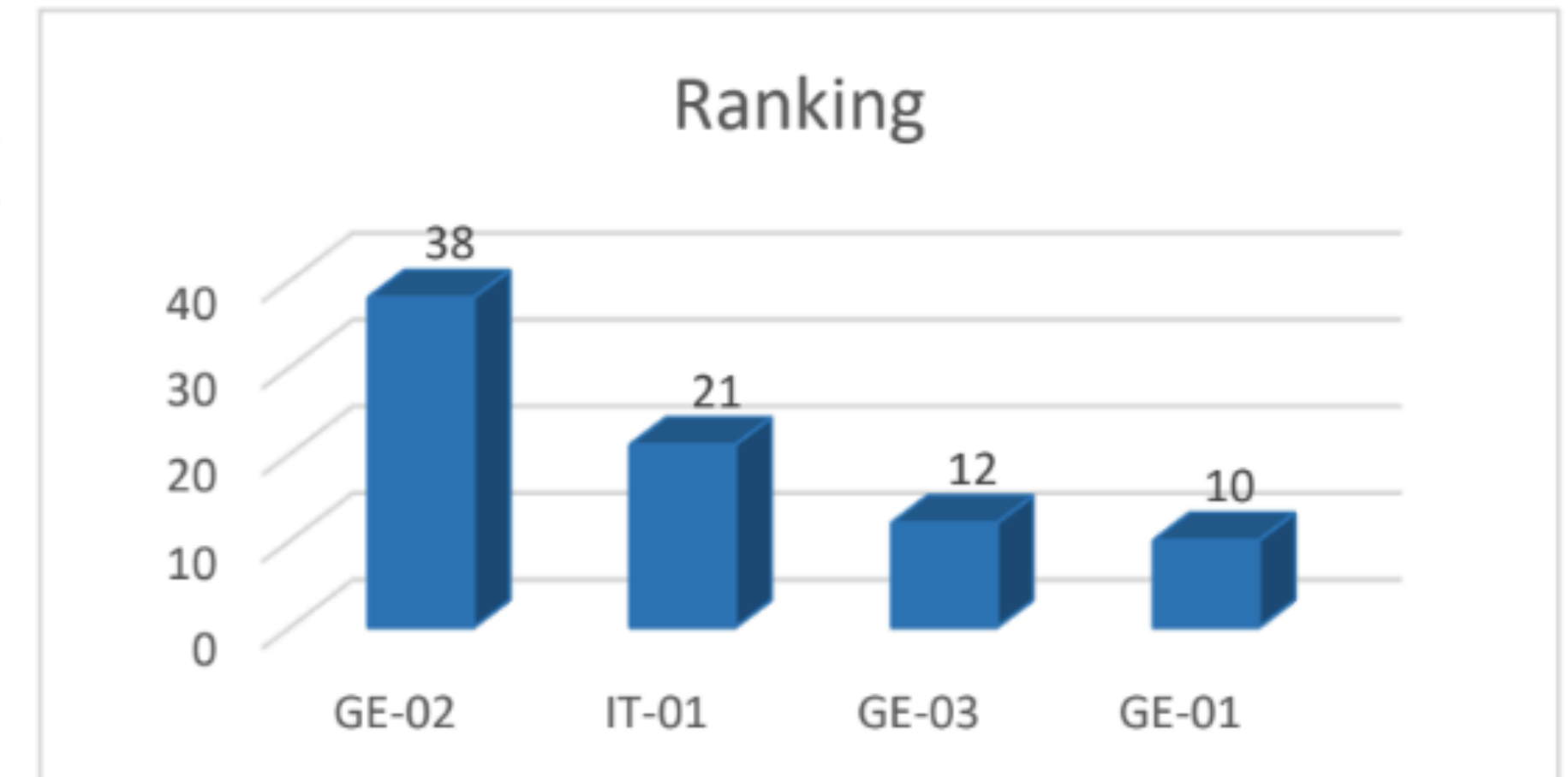
Worldwide first study with insights on CE-approved FeNO home monitoring device