"Breathlessness diagnostics in a Box" for primary care. A multi-country quality improvement project using a stepped-wedge design. "Breathlessness diagnostics in a Box" (BiaB)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000217

EU PAS number

EUPAS1000000217

Study ID

1000000217

DARWIN EU® study

No

Study countries

☐ Netherlands

☐ Spain

☐ United Kingdom

Study description

Breathlessness has a prevalence of ~10% and is a common reason for people to consult their general practitioner. As breathlessness is a symptom in various conditions it is difficult to determine its cause, which hampers optimal treatment. There is a lack of quick and easy tests that can be used in primary care to diagnose the cause of breathlessness. Therefore, we have developed "Breathlessness diagnostics in a Box" (BiaB), an easy and reliable tool intended to support healthcare professionals with fast execution of diagnostic procedures required to diagnose the cause(s) of breathlessness. In 2023 a pilot study was performed to design and test BiaB. In the current study, we aim to investigate whether implementation of BiaB in primary care will shorten the time for the diagnostic process for patients presenting with breathlessness.

Study status

Planned

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

☐ Netherlands

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Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

Janwillem W.H. Kocks

Study contact

breathlessness@gpri.nl

Primary lead investigator

Janwillem W.H. Kocks

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2023

Actual: 01/12/2023

Study start date

Planned: 05/04/2024

Data analysis start date

Planned: 01/09/2026

Date of interim report, if expected
Planned: 01/10/2026

Date of final study report
Planned: 01/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

C1.Research_Protocol_GPRI-BiaB_V6.0_4Apr24 clean Signed.pdf(2.14 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Medical procedure

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

A prospective stepped-wedge study design with a usual care period and an intervention period.

Main study objective:

Primary objective: To demonstrate whether BiaB use shortens time to diagnosis as compared to usual care without BiaB use
Secondary objectives: To demonstrate whether BiaB use increases the number of new diagnoses of COPD and/or cardiovascular disease (CVD) as compared to usual care without BiaB use and to demonstrate usability and efficiency of BiaB

Study Design

Non-interventional study design

Cluster design

Study drug and medical condition

Medical condition to be studied

Dyspnoea

Population studied

Short description of the study population

The study aims to capture the real-world heterogeneity in primary care practices and patients. Therefore, inclusion and exclusion criteria are limited. Patients are eligible to be included in the study if the following criteria apply:

- 1. Age: Patient must be at least 18 years old at the time of signing the informed consent.
- Type of patients and symptom characteristics:

2a Patients that present with undiagnosed dyspnea (breathlessness); or

2b Patients who have existing diseases that could cause breathlessness, but have residual or increasing breathlessness that could be caused by other not yet detected diseases. Or HCP has doubts or requires additional tests to confirm diagnosis or to suspect new, parallel, diagnoses. For example, breathlessness in patients assessed:

a. within the framework of Cardiovascular Risk Management or

b. for COPD monitoring

Exclusion criteria

1. Acute worsening of previous diagnosed chronic disease where there is no suspicion of

comorbidities (for example when a patient with clear COPD diagnosis has an exacerbation

where typically the HCP will not perform additional tests).

2. Inability to understand and sign the written consent form.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

900

Study design details

Setting

A prospective stepped-wedge study design will be used for this study (Figure 4). In every country, participating sites will be assigned randomly to one of the five sequences (3 sites per sequence) for timing of the intervention start. Each sequence starts with a usual care period (6 weeks or a multiple of 6) which will be followed by a transition period of 4 weeks prior to the BiaB intervention period (6 weeks or a multiple of 6). During the transition period the healthcare professionals (HCPs) at the site will be instructed about the start date of the BiaB intervention and they will receive training for the use of BiaB. The study duration for sites is 40 weeks in total. The maximum study duration for patients is one visit followed by a maximum of 4 quarterly questionnaires (1 year).

There will be 15 sites per country, amounting to a total of 45 sites for The Netherlands, Spain and the United Kingdom. Per site 20 patients will be

included for analysis during the 40-week study period, amounting to 300 patients per country and 900 in total for 3 countries. Per site the number of patients seen in the usual care period and BiaB intervention period will differ, but at the end of the study this study design should yield a ratio of 1:1 (usual care or BiaB intervention). Data will be collected (i) during the visit, and (ii) using questionnaires sent to patients and HCPs.
Electronic medical data will be extracted from the participating GP practices before, during and at the end of the study. Data collected during the usual care period and, if possible, retrospective data will be used as a control to examine endpoints.

Outcomes

The primary endpoint is days between presentation with or consultation for breathlessness and a diagnosis causing the breathlessness (usual care group versus Biab intervention group).
The first secondary endpoint is the number of new diagnoses of COPD and cardiovascular disease (CVD) in patients (usual care group versus BiaB intervention group).
The second secondary endpoint is to demonstrate the usability and efficiency of BiaB.

Data analysis plan

See protocol

Data management

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No