

# "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)

**First published:** 19/06/2024

**Last updated:** 16/10/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000217

### Study ID

1000000217

### DARWIN EU® study

No

### Study countries

☐ Netherlands

☐ Portugal

☐ Spain

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## 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.

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## Study status

Planned

# Research institutions and networks

## Institutions

### General Practitioners Research Institute (GPRI)

☐ Netherlands

**First published:** 31/08/2022

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**Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

# Contact details

## Study institution contact

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Study contact

[breathlessness@gpri.nl](mailto: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

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## Study start date

Planned: 05/04/2024

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## Data analysis start date

Planned: 01/09/2026

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## Date of interim report, if expected

Planned: 01/10/2026

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## 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)

[C1.Research\\_Protocol\\_GPRI-BiaB\\_V7.0\\_6nov24 clean - signed.pdf](#) (1.34 MB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Medical procedure

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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.
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## **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)

- Adults (46 to < 65 years)
  - Elderly ( $\geq$  65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
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## **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 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.

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## **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.

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## **Data analysis plan**

See protocol

## **Data management**

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## **Use of a Common Data Model (CDM)**



**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No