A pragmatic, cluster randomized trial evaluating the impact of an enhanced adherence package (dual bronchodilator+add-on+app) on time to treatment failure and other clinical outcomes in exacerbating COPD patients with poor adherence to mono or dual therapy over one year (MAGNIFY)

First published: 24/09/2019

Last updated: 02/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS31405

Study ID

34422

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Not taking medications as prescribed is an issue affecting patients irrespective of disease and treatment type and can lead to poor clinical outcomes such as worsening symptoms. In COPD, guidelines have noted the importance of supporting patients with their regular inhaler use as part of COPD management.This study (MAGNIFY) will enable randomly selected GP practices to support COPD inhaler use in their patients through a new technology by Propeller Health (US). This technology includes a device which is attached to the Ultibro® inhaler, monitors inhalations and sends reminders to the user's smartphone to take their daily dose. As part of this research, the device can be offered to suitable patients for 12 months. At theend of the study, researchers will assess the impact of the technology on clinical outcomes such as COPD exacerbations and medication use. Outside this research, the technology is currently available to healthcare providers in the UK through programs with Propeller Health with a range of inhalers.The study aims to recruit 176 GP practices in the UK and collect non-identifiable data from 2624 people. Halfof the participating GP practices will be randomly selected to receive access to the technology. The other GP practices will continue their usual patient care.The study does not involve any visits outside usual care. Data will be extracted from the participating GP practices' routine medical records at each site at the beginning of the study and regularly until the end of the study. All data will be stored in an ethically approved Optimum Patient Care Research Database (https://opcrd.co.uk). Any data shared with the researchers will be fully de-identified.

Study status

Planned

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility**

ENCePP partner

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rupert Jones

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/06/2019

Study start date

Planned: 01/03/2020

Date of final study report

Planned: 15/12/2021

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG, OPRI Pte Ltd

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

ISRCTN Study ID: ISRCTN10567920 ADEPT Approval: ADEPT0719

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Main study objective:

The primary objective of this study is to assess the time to treatment failure in patients on Ultibro®+add-on device+app (“adherence support arm” ASA) compared with patients receiving usual routine clinical care. This assessment will focus on patients who are suitable for, and accept the add-on device/app technology (primary populations). 2

Study Design

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1312

Study design details

Outcomes

Time to treatment failure, where treatment failure is defined as the first occurrence of: • Moderate/severe COPD exacerbation • Prescription of triple therapy (ICS/LABA/LAMA) • Prescription of additional chronic therapy • Respiratory-related death, 1) Adherence (based on prescription (Rx) refill records over 12 months) 2) Moderate/severe exacerbations (in terms of the proportion of patients with at least one moderate/severe exacerbation at 12

months, and total number of exacerbations at 12 months)

Data analysis plan

For primary analysis, time-to-event analysis will be performed to analyse the association between intervention and time to first outcome event (treatment failure) with censoring at the time of death or loss to follow-up.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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