Emulating target trials using observational studies: use case in OptumLabs (OPERAND @ Brown U)

First published: 18/06/2019

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS29517

Study ID

29518

DARWIN EU® study

No

Study countries

☐ United States

Study description

The purpose of this study to replicate two previously published randomized controlled trials of pharmacological products that were used as the basis of marketing approval by the FDA, the ROCKET Atrial Fibrillation study and the LEAD-2 study. For each trial, the initial objective is to mimic the inclusion/exclusion criteria, endpoint definitions, exposure windows, and other design features of each study as closely as possible. Then, using a series of multivariate methods, average treatment effect (ATE) estimates will be produced and compared to those reported in the original publication.

Study status

Planned

Research institutions and networks

Institutions

Brown University

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Issa Dahabreh issa_dahabreh@brown.edu

Study contact

issa_dahabreh@brown.edu

Primary lead investigator

Issa Dahabreh

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/04/2019

Study start date
Planned: 01/04/2019

Date of final study report
Planned: 31/12/2019

Sources of funding

- Other

More details on funding

OptumLabs

Study protocol

OPERAND Research Protocol_Dahabreh_Brown & Harvard 06182019.pdf(2.27 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Methodological assessment

Main study objective:

The purpose of this study to replicate two previously published randomized controlled trials of pharmacological products that were used as the basis of marketing approval by the FDA, the ROCKET Atrial Fibrillation study and the LEAD-2 study.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RIVAROXABAN

WARFARIN

LIRAGLUTIDE

METFORMIN

GLIMEPIRIDE

Medical condition to be studied

Atrial fibrillation

Diabetes mellitus inadequate control

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

99999

Study design details

Outcomes

stroke & embolism for the ROCKET emulation, change in A1C at the end of the study for the LEAD-2 emulation

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Data analysis plan

assessment of effectiveness using causal inference methods in observational data, comparison of alternative statistical methods

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.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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