Comparison of participant characteristics in decentralized clinical trials, conventional clinical trials, and real-world patients: a descriptive study

First published: 28/07/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS106035

Study ID

106207

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Decentralized clinical trial (DCT) approaches have the promise of improving trial representativeness, by improving trial access, allowing the inclusion of immobile participants or participants from rural areas, and lowering the burden of trial participation. Therefore, an eligible participant who would not participate in a conventional trial with regular on-site trial-related procedures may participate in a decentralized trial. Broad representativeness improves the generalizability of the study results, which may benefit regulatory and clinical decision-making. However, it is unclear whether the promise of increased representativeness can be met in practice. This study aims to compare the participant characteristics of those who participated in a fully decentralized trial and a comparable clinical trial to real-world patients who were intended to be treated and those who would have been eligible to participate. To this end, we selected a decentralized and conventional trial that both evaluated the effect of aspirin for the primary prevention of vascular events in patients with diabetes.

Study status

Finalised

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

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Institution | Educational Institution | ENCePP partner

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 23/12/2022

Study start date

Planned: 28/08/2023

Actual: 01/08/2023

Date of final study report

Planned: 03/06/2024

Actual: 29/01/2025

Sources of funding

- EU institutional research programme

More details on funding

IMI Trials@Home

Study protocol

20240411_Research protocol_ENCEPP_v2.pdf (987.19 KB)

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

https://doi.org/10.1016/j.drudis.2025.104304

Methodological aspects

Study type

Study type list

Study topic:

Other

Study type:

Non-interventional study

Scope of the study:

Other

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

Compare baseline characteristics of trial participants with real world patients to study the representativeness.

Main study objective:

This study’s aim is to describe the differences in baseline characteristics between a decentralized clinical trial and a conventional clinical trial compared to real-world patients (i.e. those who are intended to use the intervention under study, and the eligible patients).

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Diabetes mellitus

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

830.000

Study design details

Outcomes

The proportion of participants and real world patients with key baseline characteristics (these will be discussed with a diabetologist) for categorical variables and mean (SD) for continuous variables. We will describe the differences between the trial participants, intended users, and eligible patients for both the decentralized and the conventional clinical trial. Baseline characteristics that were not considered key characteristics or were not reported in both the decentralized trial and the conventional trial (but only in one of these trials) may be explored.

Data analysis plan

We will use descriptive statistics to report on the baseline characteristics. Continuous variables will be described using the mean (standard deviation) and median (interquartile range) and categorical variables will be described by the

number and percentage of patients in each category. Participation to prevalence ratios and Cohen's D may be calculated to compare categorical and continuous characteristics, respectively, for the intended users, eligible patients and trial participants. CPRD Gold data will be used that is representative of the UK population.

Documents

https://doi.org/10.1016/j.drudis.2025.104304

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)

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