Meta-Analysis of Amputation Events from Clinical Trials DIA3008 (CANVAS), DIA4003 (CANVAS-R), and DNE3001 (CREDENCE)

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Study Finalised

Administrative details

EU PAS number

EUPAS29875

Study ID

34354

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Belgium
- [ ] Brazil

- [ ] Canada
- [ ] China
- [ ] Colombia
- [ ] Czechia
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] India
- [ ] Israel
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Luxembourg
- [ ] Malaysia
- [ ] Mexico
- [ ] Netherlands
- [ ] New Zealand
- [ ] Norway
- [ ] Russian Federation
- [ ] Spain
- [ ] Sweden
- [ ] Taiwan
- [ ] Ukraine
- [ ] United Kingdom
- [ ] United States

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

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Primary lead investigator

Rong (Rose) Qiu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/07/2018

Actual: 23/07/2018

Study start date

Planned: 26/04/2019

Actual: 26/04/2019

Date of final study report

Planned: 01/08/2019

Actual: 20/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

JANSSEN-CILAG INTERNATIONAL NV

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

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

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Data collection methods:

Secondary use of data

Main study objective:

To estimate the risk for lower limb amputation in various patient populations in a meta-analysis pooled across the CANVAS, CANVAS-R, and CREDENCE studies.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medical condition to be studied

Amputation

Population studied

Short description of the study population

Canagliflozin- or placebo-treated subjects in the 3 completed outcome trials (CANVAS, CANVAS-R, and CREDENCE) were evaluated. The patient population of CANVAS and CANVAS-R was subjects with T2DM and either CV disease (secondary prevention) or at least 2 risk factors for a CV event (primary prevention). The patient population of CREDENCE were subjects with T2DM, Stage 2 or 3 chronic kidney disease, and macroalbuminuria, who were receiving standard of care therapy including a maximum tolerated labeled daily dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker.

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)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

14531

Study design details

Outcomes

To estimate the relative risk of the time to first occurrence of lower limb amputation for canagliflozin relative to placebo (ie, hazard ratio and 95% confidence interval) in the various patient populations in a meta-analysis pooled across the CANVAS, CANVAS-R, and CREDENCE studies. To evaluate the risks of preceding adverse events of interest that potentially led to amputation in different study groups (canagliflozin compared with placebo), including an analysis of risk factors defined by patient in subgroups of patients.

Data analysis plan

The analysis sets defined for this meta-analysis of lower limb amputation in terms of the following two components: (1) analysis population, which specifies the subjects included in the analysis, (2) data period, defining the time window during which data will be included in the analysis. In both the On-Study and On-Treatment analysis sets (which include treated subjects with different time windows as detailed below), Day 1 is the first double blind dose date for each subject. If missing or incomplete, the first dose date will be imputed as the randomization date. The primary meta-analyses of lower limb amputation will be based on the On-Study analysis set, selected analyses may also be provided for the On-Treatment analysis set.Analysis Set: On-Treatment/ On-Study. Population: Treated subjects/ Treated subjects. Data Period: Day 1 to the last dose date plus 30 days or the last trial contact date, whichever is earlier/ Day 1 to the last trial contact date up to Global Trial End Date.

Documents

Study results

CSR Synopsis_28431754NAP4001_EUPAS29875.pdf(145.27 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Meta-Analysis of Amputation Events from databases of the completed Clinical Trials DIA3008 (CANVAS), DIA4003(CANVAS-R), and DNE3001 (CREDENCE)

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