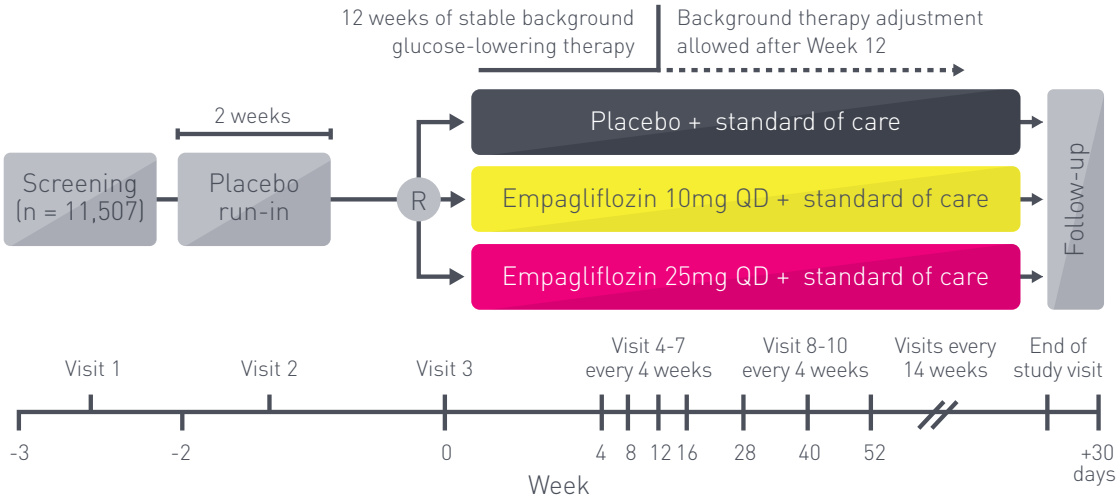
EMPA-REG OUTCOME® trial design Fact Sheet

Introduction

Approximately one in two people with diabetes worldwide dies due to cardiovascular (CV) disease, making it the leading cause of death in this population.[1,2] The relationship between diabetes and CV disease is complex; diabetes is a risk factor for CV disease and conditions such as high blood pressure and obesity, that are more common in people with diabetes, are also risk factors for CV disease.[1]

Given the association between CV disease and diabetes, studies to establish the CV safety profile of new diabetes treatments are highly important. The **EMPA-REG OUTCOME® trial**, was a long-term clinical trial which investigated CV outcomes for Jardiance® (empagliflozin) in more than 7,000 adults with T2D at high risk for CV events.

Trial design[3]



Zinman *et al.* Cardiovas Diabetol 2014; 13:102

EMPA-REG OUTCOME® was a multicentre, randomised, double-blind, placebo-controlled trial.[4] The study was designed to assess the effect of Jardiance® (empagliflozin) (10mg or 25mg once daily) added to standard of care compared with placebo added to standard of care on CV events in adults with T2D at high risk of CV events and with less than optimised blood glucose control. The study was designed to first test for non-inferiority and then for superiority.

Boehringer Ingelheim

Lilly

Standard of care comprised glucose lowering agents and CV drugs (including antihypertensive and lipid lowering agents).

Primary endpoint:

Time to first occurrence of CV death, heart attack (non-fatal myocardial infarction) or non-fatal stroke.[3]

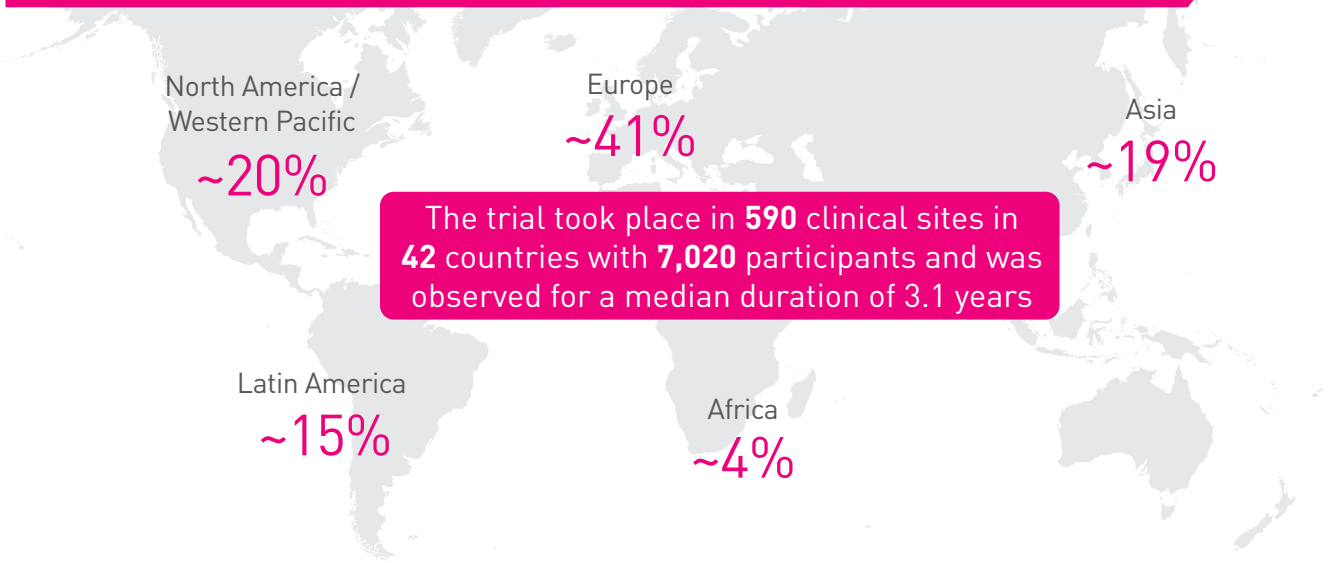
Key secondary endpoints:

Time to first occurrence of CV death, heart attack (non-fatal myocardial infarction), non-fatal stroke or hospitalisation for unstable angina pectoris.[3]

Key inclusion criteria:[3]

- Less than optimised glycaemic control
- High risk of CV events

Study population[3]



Mean age of 63 years

- 9 percent were ≥75 years

Time since diagnosis:

- ≤5yrs in 18 percent
- >10yrs in 57 percent

References

1. World Heart Federation. Diabetes as a risk factor for cardiovascular disease. Available from: http://www.world-heart-federation.org/cardiovascular-health/cardiovascular-disease-risk-factors/diabetes/ (accessed: January 2015).

2. World Health Organization. Diabetes: fact sheet no. 312. Available from: http://www.who.int/mediacentre/factsheets/fs312/en/# (updated October 2013; accessed: January 2014).

3. Zinman B, *et al.* Rationale, design, and baseline characteristics of a randomized, placebo-controlled cardiovascular outcome trial of empagliflozin (EMPA-REG OUTCOME). *Cardiovasc Diabetol.* 2014;**13**:102.

4. ClinicalTrials.Gov. BI 10773 (Empagliflozin) Cardiovascular Outcome Event Trial in Type 2 Diabetes Mellitus Patients (EMPA-REG OUTCOME). Available from: https://clinicaltrials.gov/ct2/show/NCT01131676 (accessed: Jan 2015).