Clinical Study Report Synopsis	
Drug Substance	Not Applicable
Study Code	D1841C00002
Edition Number	1.0
Date	12 October 2017

A real-world, point-of-care, randomized, parallel group, open, 6-month clinical study to evaluate the effect of a digital disease management tool in patients with type 2 diabetes mellitus

Study dates: First subject enrolled: 4 May 2016
Last subject last visit: N/A – study terminated

Sponsor : AstraZeneca

This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

Study sites and number of patients planned

Number of patients planned: Approximately 466 (233 per patient cohort)

Number of sites planned (health care facilities): Approximately 20

Number of patients planned per site: Approximately 15-45

Study design

This is a real-world, point-of-care, randomized, parallel group, open, 6-month clinical study to evaluate if the provision of a digital disease management tool improves glycaemic control in patients with type 2 diabetes mellitus (T2DM), as measured by change from baseline to End of Study (Month 6) in glycosylated haemoglobin (HbA1c) levels. Clinical assessments for this study will be conducted as part of normal, standard care.

Objectives

Primary Objective:	**Outcome Measure:**
To evaluate the effect of a smart phone- and web portal-based digital disease management tool added to standard care, compared to standard care alone, on glycaemic control in patients with T2DM	Measured by change from baseline to End of Study (Month 6) in HbA1c levels
Secondary Objective:	**Outcome Measure:**
To evaluate the effect of a digital disease management tool on glycaemic control and other risk-related treatment goals in patients with T2DM will be assessed between the Standard of Care + digital disease management cohort and Standard of Care cohort	• Percentage of patients who achieve HbA1c levels <7% at Month 6 • Mean change in body weight (kg) from baseline to Month 6 • Proportion of patients in both cohorts who intensify antihyperglycaemic treatment from Visit 1, defined as an increase in dose or addition of a new antihyperglycaemic agent not received at baseline

Exploratory Objective:	**Outcome Measure:**
To evaluate the use of a digital disease management tool in patients with T2DM	• Number of times smart phone- and/or web portal-based tool accessed per patient • Mean percent change from baseline to Month 6 in systolic blood pressure (SBP) • Percentage of patients who achieve BP <140/90 mmHg at Month 6 • Mean percent change from baseline to Month 6 in low-density lipoprotein-cholesterol (LDL-C) • Percentage of patients who achieve LDL-C <100 mg/dL at Month 6 • Length of time from first to last usage of smart phone- and/or web portal- based tool • Mean difference in primary care office visits between active and control group during the 6-month study period as reported in patient records *(to examine potential differences in resource utilization)* • Mean difference in Emergency Room visits between active and control group during the 6-month study period as reported by patients at the end of the study *(to examine potential differences in resource utilization)*
To evaluate the effect of digital disease management tool on patient-reported outcomes (PROs) in patients with T2DM will be assessed between the Standard of Care + digital disease management cohort and Standard of Care cohort	• Change from baseline to Month 6 in Diabetes Treatment Satisfaction Questionnaire – Status version (DTSQs) score (8-question) (treatment satisfaction) • Change from baseline to Month 6 in Diabetes Self-Management Questionnaire (DSMQ) score (16-question) (patient perception on ability to manage their disease) • Change from baseline to Month 6 in Morisky 8-item scale (adherence)

Target patient population

Females or males aged 18 years or older with T2DM, who are on one or more non-insulin antihyperglycaemic medications, who have HbA1c levels ≥8.0% and ≤11.0% in the last 6 months, and who own/have and use a smart phone.

Duration of study

The study duration for each patient will be 6 months.

Investigational product, dosage, and mode of administration

No investigational product will be administered as part of this study.

Statistical methods

The primary endpoint is mean change from baseline to Month 6 in HbA1c. Assuming an 8% dropout rate for a 6-month study and a 5% dropout rate for people who initiate insulin, a sample size of 466 randomized patients (233 patients per patient cohort) for a 6-month study will have 80% power to detect a difference of 0.5% in the mean change from baseline in HbA1c. The primary objective of the study will be analysed using a linear mixed-effects model to compare mean changes in HbA1c between the patient cohorts.

The key secondary efficacy objectives of proportion of patients who achieve the pre-defined efficacy thresholds for HbA1c (<7%), and proportion of patients who intensify antihyperglycaemic treatment during the study between the 2 patient cohorts, and proportion of patients who initiated a new class of pharmacotherapy not received at baseline between the 2 patient cohorts will be analysed by the Cochran-Mantel-Haenszel (CMH) General Association test. The key secondary efficacy objective of mean change from baseline in body weight will be analysed using a linear mixed-effects model similar to that used for the primary endpoint.

Results

Due to lower than expected recruitment the study was terminated before any data could be collected.