Real-time telemonitoring (RTTM) versus conventional care in the management of glycaemia and blood pressure in diabetic patients

Submission date 29/04/2008	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 12/02/2009	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 10/11/2010	Condition category Nutritional, Metabolic, Endocrine	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Randomised parallel group controlled trial of real-time telemonitoring (RTTM) versus conventional care in the management of glycaemia and blood pressure in patients with diabetes mellitus

Study objectives

Randomised parallel group controlled trial of real-time telemonitoring (RTTM) versus conventional care in the management of glycaemia and blood pressure in patients with diabetes mellitus.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wandsworth Local Research Ethics Committee, St George's Hospital gave approval on the 26th September 2005 (ref: 05/Q0803/128)

Study design Randomised controlled study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Diabetes mellitus

Interventions

This study is a randomised controlled trial. Patients will be recruited from the diabetes clinic at St George's Hospital to obtain consents. In the initial visit the demographic and the clinical data are collected in a standard proformas. The patients are then invited for a second visit to be randomised to either RTTM or conventional care.

The patients in the RTTM group are trained on how to self-monitor their blood glucose and weekly blood pressure using devices to transmit the data wirelessly via a mobile phone to a central server in St George's Hospital which are viewed by clinicians using a web-based tool.

The patients in the conventional care (control) group will receive their management entirely from their general practitioner and/or practice nurse in the community.

All patients from both groups will be invited for reassessment of baseline parameters after 6 months at St George's Hospital by the researcher.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

1. Improvement of blood pressure, measured at baseline and 6 months

2. Good diabetes control, measured at baseline and 6 months

Secondary outcome measures

No secondary outcome measures.

Overall study start date 01/06/2006

Completion date 01/06/2009

Eligibility

Key inclusion criteria 1. Ambulant male and females over 18 years of age 2. Diabetes mellitus

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 200

Key exclusion criteria 1. Pregnancy 2. Malignany

Date of first enrolment 01/06/2006

Date of final enrolment 01/06/2009

Locations

Countries of recruitment England

United Kingdom

Study participating centre Thomas Addison Diabetes Unit London United Kingdom SW17 0QT

Sponsor information

Organisation Motorola Inc. (USA)

Sponsor details c/o Mr Jorge Perdomo

C/O Mr Jorge Perdomo Delaware Corporation 8000 W. Sunrise Boulevard Plantation Florida United States of America FL 33322

Sponsor type Industry

Website http://www.motorola.com/

ROR https://ror.org/01hafxd32

Funder(s)

Funder type Industry

Funder Name Motorola Inc. (USA)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/07/2010		Yes	No