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Evaluation of the usefulness of an electronic system to support decision making in the integral control of patients with type 2 diabetes mellitus treated in primary health care

Submission date
26/03/2017

Recruitment status
No longer recruiting

Registration date
29/03/2017

Overall study status
Completed

Last Edited
15/11/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Patients with T2DM have increased risk of developing problems with their circulation, such as heart attack, stroke or blockages in the arteries in the legs. As well as the damaging effects of high blood sugar levels, these risks are further increased by other factors, such as high blood pressure, high cholesterol and smoking. It is well founded that properly managing these factors can help lower the risks of circulatory system disease and increase chances of survival. This study is looking at a computer tool that aims to help doctors to make decisions about which sugar, blood pressure and cholesterol control goals are recommended in each patient's case, and how best to achieve these goals. The aim of the study is to assess whether patient's diabetes is better controlled when their physicians use this decision support program.

Who can participate?
Adults who have had T2DM for at least one year.

What does the study involve?
Participants attend a study visit at which their doctor uses the decision support program to make recommendations about how they could reduce their risk of circulation problems, such as through medication or lifestyle modifications using blood pressure readings and information about blood sugar and cholesterol levels. This information is used along with the doctor's own judgment to see if patients should make any changes to how they manage their condition. After three months, patients return to the clinic in order to find out whether their blood pressure, blood sugar control and cholesterol levels have improved.
In a second part of the study, information is collected from participant's medical records in order to assess how well their blood pressure, blood sugar and cholesterol were previously controlled.

What are the possible benefits and risks of participating?
There are no guaranteed benefits involved with participating in this study, although patients are expected to be gain better control of their blood pressure, cholesterol and blood sugar levels. There are no risks involved with participating.

Where is the study run from?
1. University Health Centre Dr. Castroviejo (Spain)
2. University Health Centre Reina Victoria (Spain)
3. University Hosptial La Paz (Spain)

When is the study starting and how long is it expected to run for?
June 2014 to October 2016

Who is funding the study?
Ministry of Health, Social Services and Equality (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HULP PI-1851

Study information

Scientific Title

Electronic clinical decision support system and multifactorial risk factor control in patients with type 2 diabetes in primary health care

Acronym
ARTERIOTARGET Project-1

Study objectives
An electronic Clinical Decision Support System (eCDSS) that collects relevant clinical information and combines it with the CPG recommendations to provide personalised recommendations could be useful to improve the multifactorial control of patients with T2DM managed in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee at La Paz University Hospital (Madrid), 25/11/2014, ref: HULP PI-1851

Primary study design
Interventional

Study design
Multi-centre interventional non-randomised study with a prospective phase (interventional) and retrospective phase (observational)

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
All participants attend a standard clinical visit in which their responsible physicians explain and propose the study. If they agree to take part, then blood pressure (BP) is measured and analysed and the physician uses the electronic decision support system (Arteriotarget) to advise recommendations in combination with their clinical judgement. If all vascular factors are well controlled or if the physician does not agree with Arteriotarget recommendations the patient did not receive any specific intervention. In any case a follow-up visit is scheduled at 12 weeks +/- 15 days and then blood pressure and laboratory parameters are reevaluated. Additionally patients are asked about clinical adverse events such hypoglycemia or hypotension.

In the second part of the study, medical records from 12 months to 3 months before baseline visit are reviewed for BP, LDLc, and HbA1c from the year before the study initiation to baseline.

Intervention Type
Behavioural

Primary outcome(s)

Proportion of patients with T2DM with multi-factorial control of blood pressure, LDL cholesterol, and HbA1c is assessed through clinical examinations and blood testing at baseline and 12 weeks

Key secondary outcome(s)
1. Proportion of controlled patients for each individual factor (blood pressure, LDL cholesterol and HbA1c) is assessed through clinical examinations and blood testing at baseline and 12 weeks
2. Mean change in ystolic BP (SBP), diastolic BP (DBP), cLDL, and HbA1c is assessed through clinical examinations and blood testing at baseline and 12 weeks
3. Proportion of patients with potential adverse events attributable to intensification of treatment (glomerular filtration rate decrease >20%, CPK elevated 3 times the upper limit of normal [ULN], GPT elevated 3 times ULN, hypo- or hyperkalaemia, and hypoglycemia or hypotension episodes) is assessed through blood testing at 12 weeks and focused clinical interview (hypoglycaemia or hypotension episodes)
4. Primary care physicians' satisfaction with the eCDSS is evaluated using an anonymous, semi-quantitative survey at the end of recruitment

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. T2DM diagnosed at least one year before

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Over 65 years
2. Poor short-term prognosis according to clinical judgement (advanced comorbidities, frailty, and severe cognitive impairment)

Date of first enrolment
01/02/2015

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
Spain

Study participating centre
University Health Centre Dr. Castroviejo
Calle de Cándido Mateos, 11
Madrid
Spain
28035

Study participating centre
University Health Centre Reina Victoria
Av. de la Reina Victoria, 21
Madrid
Spain
28003

Study participating centre
University Hosptial La Paz
Paseo de la Castellana 261
Madrid
Spain
28046

Sponsor information

Organisation
Hospital Universitario La Paz

ROR
https://ror.org/01s1q0w69

Funder(s)

Funder type
Government

Funder Name
Ministry of Health, Social Services and Equality (Ministerio de Sanidad, Servicios Sociales e Igualdad)

Alternative Name(s)
Ministry of Health, Social Services and Equality

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from rosa.torres@salud.madrid.org and carolvelascoes@hotmail.com

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
Participant information sheet		27/03/2017	06/04/2017	No	Yes
Participant information sheet		27/03/2017	06/04/2017	No	Yes