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Can diabetes alert dogs detect hypoglycemia in patients with type 1 diabetes?

Submission date
22/04/2016

Recruitment status
No longer recruiting

Registration date
26/04/2016

Overall study status
Completed

Last Edited
26/04/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Trained dogs are increasingly being used to detect when people with type 1 diabetes have low blood sugar (glucose). No one knows how well these dogs work, yet patients are paying tens of thousands of dollars to purchase dogs from dog trainers. Doctors don't know what to tell their patients about the dogs because we don't know enough about them. The aim of this study is to find out how reliable trained dogs are at detecting low blood sugar levels. We will compare the dog alerts to blood sugar measurement tools that are already well-tested: fingerstick blood tests and a continuous glucose monitoring (CGM) device.

Who can participate?
Type 1 diabetes patients aged 2-80 who already use a trained dog to detect low blood sugar levels

What does the study involve?
The study lasts one week. Participants go about their usual lives while wearing a "blinded" CGM which measures glucose levels but the numbers are not visible to the participant. When their dog alerts, the participant carries out a fingerstick blood test and records any low blood sugar symptoms. Participants also complete a brief survey about low blood sugar and how well they think their dog works.

What are the possible benefits and risks of participating?
Participants will receive a copy of the CGM report at the end of their participation and will be paid for their time. Possible risks include problems with the CGM insertion including pain, bleeding or infection at the insertion site, or discomfort with extra fingerstick blood tests.

Where is the study run from?
Oregon Health & Science University (USA)

When is the study starting and how long is it expected to run for?
June 2014 to August 2015

Who is funding the study?
Jaeb Center For Health Research (USA)

Who is the main contact?
Dr Evan Los

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OHSU IRB00010881; Jaeb Center for Health Research PPQ#10061006829

Study information

Scientific Title
Reliability of trained dogs to detect hypoglycemia in patients with type 1 diabetes

Study objectives
1. Trained dogs will not be able to reliably detect and alert to hypoglycemia in patients with type 1 diabetes
2. Compared to a continuous glucose monitor (CGM) with established reliability data, trained dogs will provide inferior detection and alert capabilities in patients with type 1 diabetes
3. Trained dogs accurately alert to rate of change and absolute glucose values

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oregon Health & Science University Institutional Review Board, approved 31/03/2015, renewed 27/11/2015, IRB#00010881

Study design
Pilot study exploring the test characteristics (sensitivity, positive predictive value) of a trained dog to detect hypoglycemia under real-life conditions. The study also explores patient perceptions of dog reliability and subjective value.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Diagnostic

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
Type 1 diabetes

Interventions
Use of trained dog to detect and alert to hypoglycemia events. We assess and compare accuracy to measurement tools with known accuracy - capillary glucose and continuous glucose monitoring. Continuous glucose monitors are blinded to allow for detection of unrecognized hypoglycemia (by either subject or trained dog). Detailed event diaries allow assessment of dog alerts and compare to time stamp of continuous glucose monitor measurement and capillary blood glucose.

Intervention Type
Other

Primary outcome measure
1. Rate of correct identification and alert to hypoglycemia event by trained dog:
1.1. Rate of correct alert (CBG or CGM <70 mg/dL and dog alert prior to other measures)
1.2. Rate of delayed alert (CBG or CGM <70 mg/dL and dog alert after other measures)
1.3. Rate of missed alert (CBG or CGM <70 mg/dL and no dog alert)
1.4. Rate of incorrect alert (alert without the presence of hypoglycemia)

Secondary outcome measures
1. Mean and median time to alert after CGM <70
2. Rate of change of CGM value at time of dog alert
3. Total duration of time with CGM value <70 mg/dL per 24 hours)
4. Subjective confidence of dog’s master in the trained dog’s ability to detect hypoglycemia

5. Rate of hypoglycemia events for which dog is not present/not available
6. Rate of correct identification and alert to hyperglycemia event by trained dog at threshold designated by dog's master

Overall study start date
01/06/2014

Completion date
19/08/2015

Eligibility

Key inclusion criteria
Age 2-80 years with diagnosis of type 1 diabetes and current user of dog formally trained to detect hypoglycemia

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
Originally targeted 15 subjects to gather 45 hypoglycemia events. Target number of events achieved after 8 subjects. Interim power analysis showed additional subjects would not provide additional statistical power so enrollment stopped at 8 subjects

Key exclusion criteria
1. Pregnancy
2. Unwilling to use blinded CGM device
3. Inability to speak, read, write and understand English language

Date of first enrolment
01/06/2015

Date of final enrolment
19/08/2015

Locations

Countries of recruitment
United States of America

Study participating centre

Oregon Health & Science University
United States of America
97239

Sponsor information

Organisation
Jaeb Center for Health Research (USA)

Sponsor details
15310 Amberly Drive Ste. 350
Tampa
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33647

Sponsor type
Research organisation

Website
https://www.jaeb.org/

ROR
https://ror.org/04ezjnq35

Funder(s)

Funder type
Research organisation

Funder Name
Jaeb Center For Health Research (USA)

Results and Publications

Publication and dissemination plan
Oral presentation of study findings at American Diabetes Association 76th Scientific Sessions; New Orleans, Louisiana; June 2016.
Anticipate submission of manuscript of study results in May/June 2016.

Intention to publish date
01/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request