

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

Submission date 22/04/2016	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/04/2016	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 26/04/2016	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Protocol serial number
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

Primary study design

Interventional

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.

Study type(s)

Diagnostic

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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)

ROR

<https://ror.org/04ezjnq35>

Funder(s)

Funder type

Research organisation

Funder Name

Jaeb Center For Health Research (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request