The diabetic hypo-alert dog : a added value to the patient with hypoglycemia-unawareness ?

Published: 09-02-2010
Last updated: 20-06-2024

To evaluate the accuracy of trained hypo-alert dogs and to evaluate the quality of life of patients with such a dog.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON32612

Source
ToetsingOnline

Brief title
The diabetic hypo-alert dog

Condition

- Diabetic complications

Synonym
hypoglycemia unawareness, hypo-unawareness

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: bijdrage uit Wetenschapsfonds ziekenhuis MCL

Intervention

Keyword: cgm, dog, hypoglycemia, unawareness

Outcome measures

Primary outcome

percentage of adequately alerted hypoglycemias by the dog during the

observation periods

Secondary outcome

quality of life

Study description

Background summary

hypoglycemia unawareness is a serious problem in more than 25 percent of patients with longstanding diabetes type 1. Until now there are no solutions for this problem. A dog is able to sense hypoglycemia in his master and can be trained to alert his master. A observation with one patient has proven that this concept can work.

Study objective

To evaluate the accuracy of trained hypo-alert dogs and to evaluate the quality of life of patients with such a dog.

Study design

8 patients who will betrained with a hypo-alert dog will be tested with contineous glucose monitoring for 3 days, before , during and after the training. Data from the cgm, which will be blinded during the study period will be correlated to the reaction of the dog and the self measured blood glucose values of the patients. Questionaries concerning hypo-fear and quality of life will be filled by the patients before, during and after the training period

Study burden and risks

CGM will be some kind of burden for the patients, while having to wear a sensor

for three days at a row and inserting a subcutaneous needle.
No clear risks are involved

Contacts

Public
Medisch Centrum Leeuwarden

H.Dunantweg 2
9834 AD
NL
Scientific
Medisch Centrum Leeuwarden

H.Dunantweg 2
9834 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

diabetic patients older than 18 years with hypoglycemia unawareness

Exclusion criteria

psychiatric problems

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	09-02-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30622.099.09