

Use of the 1e or 2e drop of blood during the capillary glucose monitoring

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The objective is to investigate whether the 1e or 2e drop of blood can be used during the capillary glucose monitoring. The influence of a soiled finger and venous stasis are investigated.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON33456

Source

ToetsingOnline

Brief title

use of the 1e or 2e drop of blood

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Medisch Research Fonds;Stichting Langerhans;Sanofi-aventis

Intervention

Keyword: self monitoring of blood glucose, soiled fingers, venous stasis

Outcome measures

Primary outcome

The capillary glucose value of the 1e and the 2e drop of blood will be compared to the control capillary glucose value. A difference more than 10 % is relevant. Of the testresults 95 % must be < 10 % difference.

Secondary outcome

Lead not washing the hands, venous stasis of fingers soiled with fruit more often to more than 10 % difference compared to capillary glucose values with clean hands.

Clarke Error Grid analysis will be used to investigate in how many cases the outcome will lead to another interpretation and/or action. The patients with diabetes type 1 and type 2 will be separately investigated.

Study description

Background summary

Self-monitoring of blood glucose (SMBG) is an important tool in the management of diabetes mellitus. Patients with diabetes and insulin treatment assess their blood glucose level to evaluate and, if necessary, to adjust insulin treatment and lifestyle, and to detect hypoglycemia.

Recently a discussion started in The Netherlands about the use of the 1e or 2e drop of blood during SMBG. This study investigate whether the 1e drop or the 2e drop of blood can be used during SMBG conducted by the patients with diabetes.

Study objective

The objective is to investigate whether the 1e or 2e drop of blood can be used during the capillary glucose monitoring. The influence of a soiled finger and

venous stasis are investigated.

Study design

The control capillary glucose value is measured on each finger which is used during the study. Capillary glucose values are measured when the patient has not washed his/her hands, when the patient has washed his/her hands, when the fingers are soiled with different kind of fruit (apple and banana) en during venous stasis. The Accu-Chek Compact plus bloodglucose meter is used. The study is conducted by the investigator in the laboratory of the Isala Clinics.

Intervention

Intervention is capillary glucose measurement in the following situations:

1. the patient has not washed his or her hands
2. the patient has washed his or her hands
3. the fingers are soiled with different kind of fruit: apple and banana
4. venous stasis

Study burden and risks

SMBG is regularly done by patients with diabetes. Laboratory values and general information are distracted from the medical report. The patients are asked several questions about their SMBG.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

patients with type 1 or type 2 diabetes and treatment with insulin and who visit the laboratory of the Isala Clinics

age > 18 year

Exclusion criteria

dialysis patients

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-09-2009

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 26-08-2009

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL27336.075.09