

OneLook: Non invasive blood glucose measurement (pilot study)

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/08/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5296

Study information

Scientific Title

A non-randomised interventional clinical laboratory study to assess whether Lein's novel non-invasive glucose measurement technique offers a viable alternative to the current invasive capillary blood glucose solution

Acronym

DRN208

Study objectives

To assess whether Lein's novel non-invasive glucose measurement technique offers a viable alternative to the current invasive capillary blood glucose solution.

The purpose of this trial was to check for correlation between measured results taken from Lein's meter, the current leading capillary glucose meters and a gold standard venous blood laboratory measurement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Service - Berkshire Research Ethics Committee approved on the 3rd June 2008 (ref: 08/H0505/70)

Study design

Non-randomised interventional and observational process of care clinical laboratory study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

GP practice

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

Topic: Diabetes Research Network; Subtopic: Both; Disease: Device studies

Interventions

Volunteers were tested over a period of 4 hours with blood glucose readings taken with conventional finger stick meters and a gold standard venous blood meter every 15 minutes. Eye data was also collected every 15 minutes in order to enable the investigating team to compare the readings. The volunteers were provided with a sandwich lunch part way through the trial in order to produce a change in their blood glucose levels.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Measurements were performed at specific points in time that compared various meters. The results were analysed using multi-level and mixed models in the statistical software package "R".

Secondary outcome measures

No secondary outcome measures

Overall study start date

11/08/2008

Completion date

23/03/2009

Eligibility**Key inclusion criteria**

1. Age 18 to 75 years, male only
2. Type 2 diabetes for at least 3 months
3. Able and willing to do fingerprick blood glucose testing

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria

1. Age less than 18 and greater than 75 years
2. Significant renal impairment defined as a serum creatinine above 200 µg/ml
3. History of severe depression or mental instability
4. People with type 1 diabetes
5. Coexistent other serious illness
6. Pregnancy
7. Epilepsy
8. Known human immunodeficiency virus (HIV), hepatitis B, C or other blood borne infection

- 9. Previous laser refractive surgery or cataract surgery
- 10. An ocular refractive error that is not between -5 and +5 dioptres
- 11. Astigmatism over 1 dioptre
- 12. Glaucoma
- 13. Cataract
- 14. Colour blindness

Date of first enrolment

11/08/2008

Date of final enrolment

23/03/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

London Road

Reading

United Kingdom

RG1 5AQ

Sponsor information

Organisation

Lein Applied Diagnostics Ltd (UK)

Sponsor details

London Road

Reading

United Kingdom

RG1 5AQ

Sponsor type

Industry

Website

<http://www.lein-ad.com/>

ROR

<https://ror.org/02nwjvq32>

Funder(s)

Funder type

Government

Funder Name

NHS Innovations (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Results presented as a poster entitled "OneLook Non-invasive Blood Glucose Measurement" at the International Diabetes Federation conference in Montreal in October 2009.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration