ISRCTN68716188 https://doi.org/10.1186/ISRCTN68716188

OneLook: Non invasive blood glucose measurement (pilot study)

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/08/2021	Nutritional, Metabolic, Endocrine	[ ] 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

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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".

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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
United Kingdom

England

Study participating centre
London Road
Reading
United Kingdom
RG1 5AQ

Sponsor information

Organisation
Lein Applied Diagnostics Ltd (UK)

ROR
https://ror.org/02nwjvq32

Funder(s)

Funder type
Government

Funder Name
NHS Innovations (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration