

CE mark study of a home self-test system for blood cell count and ear temperature

Submission date 29/11/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 12/12/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/01/2017	Condition category Other	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

There is no home test system for self-test blood cell count and ear-temperature test in the home. This study aims to validate the use of a new system for this purpose.

What does the study involve?

The new system will measure total white blood cell count (WBC), Granulocyte cell count (GRN) and haemoglobin (HGB) within finger prick blood. The new system is based on proven technology, and this study will achieve CE marking (the declaration from the manufacturer that the device complies with EU regulations).

Who can participate?

Patients attending routine clinics at St Thomas Hospital, London, aged 18-85, male or female, of a range of educational backgrounds, who will be selected to provide a range of WBC, GRN and HGB values to help evaluate the accuracy performance of the new device.

The study involves assessment of the ability of patients to perform a self-test using finger prick blood and to obtain a correct result. Each patient will also be assessed for their ability to perform ear temperature measurement and complete a health assessment questionnaire. The ability of patients to correctly test before and after training will be determined. Patients will also use the system in the home and will complete a questionnaire regarding ease of use.

What are the possible benefits and risks of participating?

There are no benefits to patients participating. In the longer term, once that CE marking has been obtained, patients could benefit from using the device in the home if their doctors think it is useful to monitor their blood status at home. Risk involved in participating is no greater than the risks that people with diabetes are exposed to in terms of finger prick sampling (ie some possible bruising).

Where is the study run from?

St Thomas Hospital, London, UK.

When is the study starting and how long is it expected to run for?

The study is expected to run for 3-4 months.

Who is funding the study?
Philips Electronics [Philips Healthcare Incubator] are funding the project.

Who is the main contact?
Dr Martin Payne
martin.payne@philips.com

Contact information

Type(s)
Scientific

Contact name
Prof David D'Cruz

Contact details
Louise Coote Lupus Unit
St Thomas' Hospital
Westminster Bridge
London
United Kingdom
SE1 7EH

Additional identifiers

Protocol serial number
HCM003.CT.042

Study information

Scientific Title
Protocol for the commercial study to enable CE marking for the sale of a whole white blood cell count, granulocyte blood cell count, and haemoglobin-measuring device and ear thermometer with telehub, within the European Union

Study objectives
This CE mark commercial study should prove that the change in intended use for existing device technology to measure total white blood cell count (WBC), granulocyte (GRN) and haemoglobin (HGB) levels from finger capillary blood in the home by self-test users, provides clinically acceptable performance, and that patients can additionally measure their ear temperature.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London City-East, 04/12/2013, Ref: 14/LO/0021

Primary study design
Interventional

Study design

Observational CE mark study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

This is CE mark trial to prove device suitability for intended use - no drug therapy, no patient specific state monitoring sought

Interventions

The purpose of the study is to provide evidence that after training patients are able to perform a finger prick and add a blood droplet to a cartridge for successful and accurate measurement of white blood cell count and haemoglobin level using a device that has been designed for self-test use, based on a laboratory device. Patients are also asked to perform an ear temperature measurement following training and complete a questionnaire.

Patients visiting the clinic perform finger prick/ear-temperature measurements over 4 days, with training after an unaided first attempt. They are monitored unaided for the subsequent three visits.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To prove the device can be CE marked for its intended use

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/05/2014

Eligibility**Key inclusion criteria**

1. Patients attending clinics within St Thomas' Hospital, London, UK
2. Aged 18 - 85

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Leukaemic patients

Date of first enrolment

17/02/2014

Date of final enrolment

30/05/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Louise Coote Lupus Unit

London

United Kingdom

SE1 7EH

Sponsor information**Organisation**

Philips Healthcare Incubator (Home Clinical Monitoring) (Netherlands)

ROR

<https://ror.org/02p2bgp27>

Funder(s)**Funder type**

Industry

Funder Name

Philips Electronics (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No