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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

Registration date
12/12/2013

Overall study status
Completed

Last Edited
30/01/2017

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Observational CE mark study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

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

Secondary outcome measures
No secondary outcome measures

Overall study start date

17/02/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
Leukaemic patients

Date of first enrolment
17/02/2014

Date of final enrolment
30/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Louise Coote Lupus Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Philips Healthcare Incubator (Home Clinical Monitoring) (Netherlands)

Sponsor details
Building 34
High Tech Campus
Eindhoven
Netherlands
5656AE

Sponsor type
Industry

Website
http://www.healthcare.philips.com/gb_en/

ROR
https://ror.org/02p2bgp27

Funder(s)

Funder type
Industry

Funder Name
Philips Electronics (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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