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A comparison of devices for measurement of spirometry in normal healthy subjects and patients with respiratory disease

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Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/06/2018	**Condition category** Respiratory	[_] Individual participant data [_] 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
N0265166243

Study information

Scientific Title
A comparison of devices for measurement of spirometry in normal healthy subjects and patients with respiratory disease

Study objectives
The aim is to compare measurements of forced expiratory volume in one second (FEVI), forced vital capacity (FVC) and vital capacity (VC) obtained from different spirometers and identify any variability between the devices. Spirometry is recommended for use in primary and secondary care lo confirm diagnosis of specific lung diseases. A variety of devices are available for the measurement and therefore choice is often driven by cost, ease of use and portability. The accuracy of the measurements is essential for the overall diagnostic process for lung disease and inaccurate results can lead to misdiagnosis or misclassification of severity of disease. This has possible implications on different treatment regimes for differing disease severities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory

Interventions
Subjects will be recruited from patients attending the Lung Investigation Unit for routine spirometry testing and from healthy volunteers working within the department. The test procedure will not entail any changes to the normal testing routine and as such patients will be tested according to the normal laboratory protocol. Patients will be sent the information sheet prior to the appointment and asked if they would be happy lo take part in the study. On the day

of the test they will then be asked to sign a consent form and then testing will be performed as usual.

The test procedure will consist of the one routine pre-booked visit to the Lung investigation Unit and subjects will be expected to adhere to the following pre test instructions (as required for their referral):
(1) to withhold their bronchodilator medication for 4-6 hours prior to testing
(2) to avoid alcohol on the day of the test
(3) to avoid vigorous exercise for thirty
minutes prior to the test
(4) to avoid smoking on the day 01 the test. Measurements will be performed in triplicate using a wedge bellows spirometer (Vitalugraph, Bucks, UK) a pneumotachograph/flow measuring device (Jaeger Masterscreen, Viasys, UK) and compared to a recently developed spirometer (this may vary according to the latest developments).

Test protocol
(1) On arrival demographic information and anthropometric measurements will be obtained together with details regarding current medication. Subjects will also be questioned in order to ensure that pre-test instructions have been complied with.
(2) Measurements of forced expiratory volume in one second (FEVI), forced vital capacity (WC) and vital capacity (VC) will be obtained according to the ARTPIBTS guidelines for the measurement of respiratory function (ARTPIBTS, 1994) using one of the following
2.1 A test spirometer
2.2 A pnueumotachograph (Jaeger Masterscreen system)
2.3 A wedge bellows
(3) Following a minimum 15 minute period of rest, similar measurements will be obtained using a second spirometer
(4) Following a minimum 15 minute period of rest, similar measurements will be obtained using a third spirometer. Upon completion of the tests patients will be allowed to leave the laboratory or will continue with further tests according to the referral form

The order in which the tests are performed will be randomised so that the results obtained are not affected by fatigue or habituation to the tests. The randomisation will be performed using a computer generated number sequence - consenting patients will be given an identified number when they arrive and allocated to perform measurements using either the lest spirometer first, the wedge bellows spirometer or the Jaeger Masterscreen system.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
The primary outcome measure is the comparison of the results obtained between different spirometric devices:
1. The variability of the measurements obtained using the new equipment versus both the gold standard and other flow measuring devices
2. The accuracy of the measurements obtained with the new equipment versus the gold standard and other flow measuring devices.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2006

Completion date
01/01/2016

Eligibility

Key inclusion criteria
All subjects will be recruited from those routinely referred to the department for lung function testing. These patients will have been referred to the department either directly from primary care from their General Practitioner or in secondary care following a consultation with a respiratory physician from within UHB Foundation Trust.
Upon receiving the referral for testing, all potential patients (ie only those that have been referred for tests involving
spirometric measurements) will be sent the information leaflet together with the standard appointment letter asking if they would be interested in taking part in the study. A contact phone number for the Chief Investigator will be supplied and patients may have the opportunity to ask any questions either by telephone or via a prior visit to the Lung investigation Unit.
On the day of the test, all participants will sign a consent form and then testing will proceed according to the protocol.
All subjects will be given adequate time to consider whether they wish to take part in the research programme. Appointment letters together with patient information leaflets will be sent out at least two weeks prior to the test date in order to enable patients to ask any questions should they wish to do so. If they agree to participate the consent form will be signed when the patient arrives for the appointment prior to any tests being performed.
If patients do not wish to take part in the programme, their usual care will not be affected. They will be instructed to attend the appointment for the tests as per normal and the test will performed according to routine laboratory protocols, with no extra measurements being made.
In addition, healthy volunteers will be included and will be recruited from individuals working within the Lung investigation Unit. These individuals will be asked to read the patient information leaflet and, if they agree to participate, the tests will be scheduled at their convenience and without disruption to the usual clinical workload.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria

1. Individuals that have been referred for tests other than spirometry eg exercise testing, sleep investigations will not receive a patient information leaflet and therefore will be excluded from the study.
2. Those patients that are unable to perform technically acceptable spirometry - this will be ascertained during the testing procedure. If patients have difficulty performing the manoeuvres the physiologist will revert to the usual testing procedure using standard equipment and the patient will not be required to continue with the additional tests required for the research protocol.
3. Standard contraindications to lung function testing (ATS, 1994) such as haemoptysis, recent chest infection, recent eye or abdominal surgery, recent pneumothorax, recent myocardial infarction and acute disorders such as vomiting or diarrhoea.

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Sponsor type

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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Birmingham NHS Trust (UK), NHS R&D Support Funding

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