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IBEX Trueview® Study, version 1.0

Submission date 20/12/2019	**Recruitment status** Suspended	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/01/2020	**Overall study status** Completed	
Last Edited 30/12/2021	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Digital radiography is widely used as a way of obtaining images of the internal structures of the body using X-rays. A major drawback of using X-rays is that they can be scattered by thicker body parts. This scatter significantly reduces image quality and is currently dealt with by using a physical anti-scatter grid (ASG) which prevents scattered X-rays from reaching the X-ray detector /camera. Anti-scatter grids also absorb a portion of the direct X-rays required to form a useful image and so the patient dose needs to be increased to compensate. Removing the need for an ASG would potentially allow lower dose examinations to take place. IBEX Innovations Limited (IBEX), a local high-technology business based in Sedgefield, has developed a novel solution that offers the potential to remove the effects of scattered X-rays without the need for an ASG. The aim of the study is to demonstrate the effectiveness of the IBEX Trueview® software.

Who can participate?
Phase 1: Adult aged 50 years or above attending for a DEXA scan of Neck of Femur (for measurement of bone mineral density)
Phase 2: Adult aged 18 years or above, attending orthopaedic outpatient's clinic and requiring plain radiographs of wrist or shoulder or pelvis

What does the study involve?
Participants in phase 1 will have their X-ray taken as usual and it will be processed using the Trueview® software. If the X-rays require an ASG , participants will be asked to have a second identical set of X-rays taken without the ASG in place.
Participants in phase 2 will have an additional X-ray scan of their pelvis which will be processed using the Trueview® software.

What are the possible benefits and risks of participating?
Benefits:
There will be no clinical benefit to the participants, but they will be contributing to the development and adoption of a technology that has the future potential to:
-Improve diagnostic X-ray image quality
-Streamline radiographic assessments and improve efficiency
-Provide additional diagnostic information to enable early detection of bone health conditions
Risks:
The only risk for patients is associated with the additional radiation exposure imposed by

additional radiographs. As with all medical procedures, there is also a possibility for unanticipated risks to occur, although every effort has been taken to ensure that patient safety is of the highest importance.

Where is the study run from?
James Cook University Hospital, UK

When is the study starting and how long is it expected to run for?
October 2019 to June 2020

Who is funding the study?
1. European Commission
2. National Institute for Health Research (NIHR), UK
3. Ibex Innovations, UK

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
255317

Central Portfolio Management System (CPMS)
40376

Study information

Scientific Title
Evaluation of IBEX Trueview System to assess its effectiveness in producing image quality and bone mineral density measurement equivalent to conventional radiology

Study objectives
The primary objective of the study is to demonstrate the effectiveness of the Trueview software in obtaining bone mineral density data at an accuracy equivalent to that of a DEXA on a standard DR system without negatively impacting the diagnostic image quality of the radiograph. To do so the study consists of two seperate phases:
Phase 1 - To demonstrate that Trueview® generates a measure of bone health to the same accuracy as a dedicated DEXA system
Phase 2 - To demonstrate that the Trueview® technology generates X-ray images to at least the same quality as an existing X-ray system

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/12/2018, Study North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048026; nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 18/NE/0368

Primary study design
Interventional

Study design
Non-randomized; Interventional; Design type: Diagnosis, Imaging

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Disorders of bone density and structure

Interventions
Participants in Phase 1 will be asked to consent to the processing of their radiographs (X-ray photos) using the Trueview® technology. In cases where their standard set of radiographs requires an ASG to be used, they will be asked to have a second identical set of radiographs taken without the ASG in place. The additional assessment would take place immediately after their first set of radiographs and will add a small amount of time onto their visit (~5 mins). The additional scan will only be used to assess the performance of the technology and their scheduled assessment will still be made using the standard set of exposures as per standard clinical practice.

Participants in Phase 2 will be asked to attend the radiology department at James Cook University Hospital for an additional X-ray scan of their pelvis. The additional assessment will take place immediately after their scheduled DEXA scan and will be taken using a standard digital radiography system. The image will then be processed using the Trueview® software to obtain a second measure of their bone health for comparison. The additional scan will take approximately the same amount of time the DEXA scan.

Participation in the study begins once participants give their consent when they attend for their scheduled radiography assessment and ends once the radiographic assessments are complete. Participants will not be contacted for any further information in relation to this study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Bone mineral density (BMD) as determined from the Trueview 1.0 software and DEXA system

Key secondary outcome(s)
n/a

Completion date
14/06/2020

Eligibility

Key inclusion criteria
Patients who meet the following criteria will be considered eligible for Phase 1 of study:
1. Caucasian male or female, at least 50 years of age attending for a DEXA scan of Neck of Femur (for measurement of bone mineral density)
2. Patient able to comprehend and sign the informed consent prior to enrolment in the study

Patients who meet the following criteria will be considered eligible for Phase 2 of study:
1. Male or female, 18 years of age or over, attending orthopaedic outpatient's clinic and requiring plain radiographs of wrist or shoulder or pelvis
2. Patient able to comprehend and sign the informed consent prior to enrolment in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Phase 1:
1. Women who are pregnant or are breastfeeding
2. Concurrent participation in another experimental intervention or drug study
3. Has an implant or other radio-opaque foreign body in the location of the assessment
4. Unwilling or unable to provide informed consent

Phase 2:
1. Women who are pregnant or are breastfeeding
2. Concurrent participation in another experimental intervention or drug study

3. Unwilling or unable to provide informed consent
4. Currently wearing a cast on assessment site that is not intended to be removed prior to radiographic assessment
5. Has an implant or other radio-opaque foreign body in the location of the assessment

Date of first enrolment
14/10/2019

Date of final enrolment
14/06/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital
Marton Rd
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
Ibex Innovations (United Kingdom)

ROR
https://ror.org/05cg6gz18

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Ibex Innovations

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications	Evaluation of quantitative X-ray (QXR) method	24/12/2021	30/12/2021	Yes	No

Participant information sheet	version v1.2	25/02/2019	13/01/2020	No	Yes
Participant information sheet	version v1.2	25/02/2019	13/01/2020	No	Yes
Protocol file	version v1.7	24/09/2019	13/01/2020	No	No