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Using machine learning in the examination of dental X-rays to detect early tooth decay

Submission date	Recruitment status	[_] Prospectively registered
27/02/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/03/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2021	Oral Health	

Plain English summary of protocol

Background and study aims
The Manchester Imaging Limited software programme is designed to improve the detection rate of signs of dental disease from x-ray images and therefore diagnose dental diseases earlier than the current standard of care (visual detection by a General Dental Practitioner). This will empower patients to look after their teeth more effectively and potentially save money for the NHS by reducing the need for dental restorations and repairs.

The software will also provide a visual aid for the patient so that they know which of their teeth are under early dental decay or other types of dental disease. This could be more motivational for the patient than the dentist making general statements about frequent brushing and a sugar-free diet.
Previous research indicates that dentists are likely to miss early enamel tooth decay. The current standard care for early enamel decay is the application of fluoride in the form of high concentration toothpaste, varnishes and mouth rinse.

The software needs to be trained using digital images from the most common digital imaging systems used by dentists in the UK. It is thought that the more images that the software sees, the more accurate it will be at detecting dental disease.

The aim of this study is to provide data (in the form of anonymized digital images) by which the sponsor can improve the likelihood of the software programme working to a defined standard across the majority of commercially-available dental digital imaging systems in the UK.

Who can participate?
Patients over the age of 16 attending any of the participating centres where a dental x-ray would be taken as part of standard dental care

What does the study involve?
The study involves dental x-ray(s) images being taken. These will be anonymized for use in training the Manchester Imaging Limited software programme

What are the possible benefits and risks of participating?
There were no direct benefits to the study participants.

Bitewing radiographs (dental x-rays) are part of routine care. For participants taking part in this study, no extra bitewing radiographs will be taken. These procedures use ionizing radiation to form images of teeth and provide a dentist with other clinical information. Ionizing radiation can cause cell damage that may, after many years or decades, turn cancerous. As there is no additional ionizing radiation in this study compared to the normal standard of care, the chances of this happening are the same whether eligible participants take part in the study or not.

Where is the study run from?
9 dental practices in the Northwest of England

When is the study starting and how long is it expected to run for?
July 2018 to January 2020

Who is funding the study?
Manchester Imaging Limited (UK)

Who is the main contact?
Prof Hugh Devlin
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Contact information

Type(s)
Scientific

Contact name
Prof Hugh Devlin

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
248306

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
18/NI/0111, IRAS 248306

Study information

Scientific Title
Dental Digital Bitewing Radiograph Study: DDBRS

Acronym
DDBRS

Study objectives
The software uses machine learning to improve the detection of dental disease. The more images (anonymized digital bitewing radiographs (dental x-rays) from digital scanner systems commercially-available in the UK) that the software learns from, the better it becomes at detecting dental disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2018, Office for Research Ethics Committees Northern Ireland (ORECNI) (Customer Care & Performance Directorate, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF; +44 028 9536 1400; www.orecni.hscni.net), ref: 18/NI/0111

Study design
Cross-sectional non-interventional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Dental caries

Interventions
This study will collect anonymized digital bitewing radiographs from the patients of UK general dental practitioners (GDPs/dentists) as part of the normal standard of care to assist this learning process.

Participants were patients attending for their routine dental examination. No additional procedures or activities were carried in addition to the care normally provided to patients at that visit. There was no randomization of participants as there was no control arm to the study.

The Investigator/GDP obtained patient consent during the initial part of the dental consultation. A Patient Information Sheet was given, along with a Patient Consent Form. The potential participant had the opportunity to ask the GDP any questions. This is considered ideal as the GDP is also the Investigator at the study site so was well informed about the study.

An individual's capacity to consent was determined by their ability to:
• Understand what the taking of radiographs involves, its purpose and nature and why it is being proposed.
• Understand the benefits, risks and alternatives.
• Understand the consequences of not receiving the proposed treatment.
• Retain the information and be able to weigh up the pros and cons in order to arrive at a decision.
• Communicate the decision.

One copy of the Patient Consent Form was kept in the study file, one in the patient record and one handed to the patient. Potential participants were able to consider whether or not to take part in the study during their consultation. As the study involves normal standard of care, the decision whether or not to participate was given at any time during the potential participant's consultation.

Given the nature of the study, the timeframe from consent to the bitewing radiograph being entered into the study is negligible. It is therefore unnecessary to monitor ongoing capacity of the participant.

The patient's radiographs were then examined for dental disease by the dentists in the normal way and the findings communicated to the patient as part of their normal care. The GDP /Investigator uploaded images/DICOMs to a secure server; these images contain patient identifiable information (PII). Only the Investigator and 7i Group Ltd had access to these DICOMs. 7i Group will anonymize the images (remove any PII) and provide them to the Sponsor. Each image provided to the Sponsor was referenced by a unique ID number. 7i Group maintained a record that linked this unique identifier back to the study site, Investigator and patient. 7i Group destroyed all copies of DICOMs/digital images when the study finished. The Sponsor has kept the anonymized DICOMs.

Intervention Type
Not Specified

Primary outcome measure

To receive the required number and required mix of digital images from the majority of manufacturers/models of commercially-available dental digital imaging systems in the UK

Secondary outcome measures
None

Overall study start date
14/04/2018

Completion date
17/01/2020

Eligibility

Key inclusion criteria
Study sites:
Use one of the dental digital imaging systems previously established as the most commonly used systems (in market research commissioned by the sponsor) at their dental practice.

Patients :
1. Bitewing radiograph clinically indicated as part of standard care
2. Informed consent to participation given

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
The theoretical maximum number of study sites is 10 with 150 images from each system. This makes the maximum number of participants 1,500. A participant will be asked for consent at the beginning of their planned dental consultation. During their dental consultation, should the GDP consider that one or more bitewing radiographs (dental x-rays) are necessary as part of normal standard of care, they will be taken; more than one may be taken. NHS Digital data and the Sponsor's previous previous market research suggest that on average, when bitewing radiographs are taken, approximately two are taken.

Total final enrolment
1296

Key exclusion criteria
Patients:
Aged <16 years

Date of first enrolment

27/05/2018

Date of final enrolment
17/01/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
King Dental & Associates
Council Buildings
Market Street
Carnforth
United Kingdom
LA5 9LB

Study participating centre
Hyde Dental Practice Ltd
203 Market Street
Hyde
United Kingdom
SK14 1HF

Study participating centre
New Mills Dental Practice
6 Union Road
New Mills
United Kingdom
SK22 3ES

Study participating centre
TSa Dental Care
5 Davies Road
West Bridgford
Nottingham
United Kingdom
NG2 5JE

Study participating centre
Inverurie Dental Care
22 North Street
Inveruruie
United Kingdom
AB51 4QR

Study participating centre
Rudheath Dental Health Centre
144 Middlewich Rd.
Northwich
United Kingdom
CW9 7DS

Study participating centre
Aesthetics Dental Solutions
5 Station Square
Lytham
United Kingdom
FY8 5PA

Study participating centre
Gaskell Ave Dental
5 Gaskell Ave.
Knutsford
United Kingdom
WA16 ODA

Study participating centre
Brunner Court Dental
95 Witton St.
Northwich
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CW9 5DR

Sponsor information

Organisation
Manchester Imaging Ltd

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Sponsor type
Industry

Website
https://manchester-imaging.com/about/

Funder(s)

Funder type
Industry

Funder Name
Manchester Imaging Ltd

Results and Publications

Publication and dissemination plan
Planned publication is in a high-impact peer-reviewed journal. We intend to submit work for publication by the end of 2020.

Intention to publish date
27/02/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the company wishing to maintain its commercial lead and development of intellectual property.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results in preprint	14/02/2021	15/02/2021	No	No
HRA research summary			28/06/2023	No	No