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Development of endoscopic Optical Coherence Tomography for Laryngeal cancer screening

Submission date	Recruitment status	[_] Prospectively registered
16/08/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/03/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2017	Cancer	

Plain English summary of protocol

Background and study aims
Larynx (voicebox) cancer is one of the most common head and neck cancers. The main risk factors are smoking and drinking alcohol. Early larynx cancer can be treated by laser, which has a cure rate of over 90% and avoids the side effects of radio/chemotherapy. Later stage larynx cancer is hugely expensive to treat and wasteful of healthcare resources, often requiring mutilating treatment resulting in loss of ability to speak or swallow. Optical Coherence Tomography (OCT) is a relatively new technology where light is used to scan a tissue's surface and a few millimetres deep into it, obtaining accurate information about the tissue's characteristics, without the need to physically cut into tissue in order to microscopically examine if it is normal, precancerous or cancerous. We aim to test whether new OCT probes can distinguish normal from unhealthy larynx tissue and determine whether it is acceptable for clinicians and patients.

Who can participate?
Patients aged over 18 with suspicious larynx appearances on endoscopy.

What does the study involve?
Participants will have endoscopic OCT images taken before going on to have biopsies (samples) of the larynx tissue taken under anaesthetic. One pathologist will compare the OCT results with the standard biopsy results to determine the effectiveness of OCT in distinguishing cancerous from noncancerous tissue. Patient acceptability of the process will be established through a patient experience questionnaire.

What are the possible benefits and risks of participating?
Following this study we aim to use the results to develop a non-invasive, patient-friendly and safe laryngeal cancer screening tool. With this we aim to increase the early detection and treatment of larynx cancer.

Where is the study run from?
North West London Hospitals NHS Trust (UK).

When is the study starting and how long is it expected to run for?
October 2011 to February 2012.

Who is funding the study?
National Institute for Health Research (UK).

Who is the main contact?
Taran Tatla
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8939

Study information

Scientific Title
Development of endoscopic optical coherence tomography for laryngeal cancer screening: a non-randomised trial

Acronym
OCTiLarynx

Study objectives

OCTiLarynx (Optical Coherence Tomography in Larynx). This 'proof of concept' project has a primary objective to determine if recent and continuing advances in the technology of Optical Coherence Tomography (OCT) can result in a clinically useful out-patient based diagnostic tool for endoscopic laryngeal disease screening.

We aim to validate the clinical efficacy of novel endoscopic OCT imaging probes for distinguishing normal from unhealthy laryngeal mucosa (inflamed, dysplastic, malignant) and determine clinician/patient acceptability for the same.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central London Research Ethics Committee, 28/07/2010, ref: 10/H0718/55

Study design
Non randomised trial

Primary study design
Interventional

Secondary study design
Non randomised study

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
Laryngeal cancer screening

Interventions
Clinical recruitment of up to 40 patients for in vivo study shall occur initially at a single site (Northwick Park ENT-Head & Neck Department). Patients attending the outpatient service for secondary / tertiary care consult in relation to prolonged voice change and noted to have a suspect laryngeal mucosal lesion shall be recruited prospectively for the study. Following informed consent, these patients shall have standard endoscopic digital photographic images and endoscopic OCT images of the lesions taken under topical local anaesthesia (LA) in the out-patient department. As is standard practice presently, all such patients shall then proceed on to direct biopsies of the laryngeal lesions under general anaesthesia to allow gold standard histological diagnosis with routine Haematoxylin and Eosin stains of wax-embedded tissue sections.

A single pathologist trained in OCT tissue imaging techniques shall make a blinded comparison, comparing and correlating the OCT diagnostic modality with the standard biopsy histological

technique for distinguishing laryngeal mucosal disease category. Preliminary statistical analysis will determine the efficacy and repeatability of the OCT tool in distinguishing cancer from non-cancer. Patient acceptability of the process will be established through a patient experience questionnaire and clinician feedback shall be sought on practicality and ease of use of the endoscopic OCT tool.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Characterisation & correlation of mucosal pathology (OCT images vs Histopathology) following direct microlaryngoscopy and biopsy of laryngeal lesion under general anaesthesia (GA)

Secondary outcome measures
Patient Experience Questionnaire at initial out-patient visit , immediately following nasendoscopy examination and image capture under LA

Overall study start date
03/10/2011

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. All patients over the age of 18 years (no upper age limit)
2. Male or female gender
3. Patients able to provide informed consent to OCT-adapted flexible nasendoscope examination under topical local anaesthesia and completing a patient experience questionnaire provided at the end of procedure
4. Smokers and non-smokers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 40

Key exclusion criteria
1. All patients under the age of 18 years
2. All patients from whom informed consent has not been obtained prior to tissue resection or OCT-adapted flexible nasendoscopy respectively

Date of first enrolment
03/10/2011

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West London Hospitals NHS Trust
London
United Kingdom
HA1 3UJ

Sponsor information

Organisation
North West London Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.nwlh.nhs.uk/

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

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?
Results article	results	01/12/2012		Yes	No