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Raman spectroscopy and autofluorescence imaging in gastrointestinal tract

Submission date	Recruitment status	[_] Prospectively registered
17/06/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Digestive System	

Plain English summary of protocol

Background and study aims
Conventional diagnostic and screening tools such as white-light endoscopy have significant limitations for examining upper gastrointestinal (GI) tract lesions due to their poor diagnostic sensitivity. Therefore, there is an urgent need for the development of a new endoscopic imaging technique to complement white-light endoscopy for non-invasive diagnosis of such lesions. A novel NIR autofluorescence spectroscopy and imaging system associated with Raman spectroscopy allow a larger sample of body tissue to be probed beyond the tissue surface. This has the added benefit of minimizing concerns regarding tissue damage during examinations. Through this study, the clinical significance of this research can be a new diagnostic tool that may have significant potential for the non-invasive diagnosis of upper GI lesions. It may also serve as a tool for guiding and directing biopsies for histopathological investigations, reducing the number of negative biopsies, increasing the number of diagnoses, and reducing the medical costs for the patients.

Who can participate?
Adult patients undergoing endoscopy for suspected or known GI lesions.

What does the study involve?
The patients are first given a mild sedative as used in routine gastroscopic examinations. The upper GI tract is carefully inspected under white light endoscopy. White light endoscopic findings based on tissue morphology are documented. Observation of the mucosa (inner lining of the GI tract) morphology are classified as normal mucosa, nonspecific inflammatory mucosa or abnormal mucosa. If any tissues are suspected abnormal by the endoscopist in charge, NIR excitation light is shined on the suspicious tissue sites indicated by the white light endoscopy to excite both autofluorescence endoscopic imaging and Raman spectroscopy. NIR autofluorescence and Raman signals are documented for each lesion examined. In addition, one biopsy is taken from each lesion identified and submitted for histopathology reporting (gold standard). In the event that no lesions are detected, one biopsy from the GI tract is taken as control. Patients are only examined once in the study. No tissue samples are stored.

What are the possible benefits and risks of participating?
The laser power used in this study is less than the American National Standards Institute (ANSI)

maximum permissible skin exposure limit, and the NIR autofluorescence and Raman signal collection will be finished in a few seconds. There is no risk for the patients.

Where is the study run from?
Endoscope Center at the National University Health System (Singapore)

When is the study starting and how long is it expected to run for?
June 2010 to June 2020

Who is funding the study?
1. National Medical Research Council (Singapore)
2. National Research Foundation-Prime Minister's office (Singapore)
3. Ministry of Education (Singapore)

Who is the main contact?
1. Professor Khek Yu Ho (public)
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Development of near-infrared Raman and autofluorescence imaging endoscopy for optical diagnosis of lesions in gastrointestinal tracts

Study objectives
The hypothesis of this study is that combining the near-infrared (NIR) Raman spectroscopy with NIR autofluorescence imaging has the potential to improve early detection and diagnosis of gastrointestinal cancer and early cancer during clinical endoscopic examination.

The aims of this study are:
1. To develop a novel NIR autofluorescence endoscopic imaging system in combination with Raman spectroscopy technique for effective in vivo tissue diagnosis in the GI tract
2. To investigate the ability of native tissue fluorescence and Raman spectroscopy under NIR excitation light to differentiate lesions from normal tissues in the GI tract
3. To determine if the NIR autofluorescence/reflectance imaging technique can be used to make in vivo diagnosis of upper GI lesions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Domain Specific Review Board (DSRB), National Health Group, Singapore, 24/06/2010, ref: DSRB ref B/05/010

Study design
This is a prospective study for the development of a novel, more sensitive and superior NIR] autofluorescence endoscopic imaging system in combination with Raman spectroscopy technique for the in vivo diagnosis of GI lesions in patients.

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

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
Gastrointestinal (GI) lesions

Interventions
Patients will first be administered a mild sedative as used in conventional gastroscopic examinations. The upper GI tract will be carefully inspected under white light endoscopy. White light endoscopic findings based on tissue morphology will be documented. Observation of the mucosa morphology will be classified as normal mucosa, nonspecific inflammatory mucosa or abnormal mucosa. Autofluorescence endoscopic imaging and Raman spectroscopy under near-infrared (NIR) excitation light will then be carried out on the same tissue sites. NIR autofluorescence and Raman signals will be documented for each specific lesion examined. In addition, one biopsy will be taken from each lesion identified and submitted for histopathology reporting (gold standard). In the event that no lesions are detected, one biopsy from the upper gastrointestinal (GI) tract will be taken as control. Diagnostic sensitivity and specificity of NIR autofluorescence endoscopic imaging and Raman spectroscopy will be documented. Patients will only be examined once in the study. No tissue samples will be stored.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Diagnostic sensitivity and specificity of near-infrared autofluorescence imaging and/or Raman spectroscopy for upper gastrointestinal (GI) lesions

Secondary outcome measures
Predicative sensitivity and specificity of near-infrared autofluorescence imaging and/or Raman spectroscopy for upper gastrointestinal (GI) lesions

Overall study start date
25/06/2010

Completion date
24/06/2020

Eligibility

Key inclusion criteria

1. The subject is undergoing endoscopy for suspected or known GI lesions such as peptic ulcer, gastritis, intestinal metaplasia, dysplasia, gastric cancer, reflux oesophagitis, Barrett's oesophagus or oesophageal cancer
2. The subject must have personally signed and dated the patient informed consent form indicating that he/she has been informed of all pertinent aspects of the study
3. The subject must be willing and able to comply with all study procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. The subject who has bleeding disorders, such as haemophilia, in whom biopsies are contraindicated
2. The subject with liver cirrhosis
3. The subject with severe co-morbid illness, such as end-stage renal failure (ESRF), congestive cardiac failure (CCF), severe osteoarthritis (OA) and rheumatoid arthritis (RA) requiring long term non-steroidal anti-inflammatory drug (NSAID) therapy
4. The subject has other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may interfere with the interpretation of study results and in the judgment of the investigator would make the subject unsuitable for entry into the study
5. The subject on regular anti-coagulant prophylaxis such as warfarin must be able to undergo a five-day washout period before gastroscopy. The subject on aspirin, ticlopidine and clopidogrel must be able to undergo a one-week washout period before gastroscopy. The subject's physician or study co-investigator will exercise their clinical judgement to ensure subject's safety
6. The subject is unwilling or unable to provide signed informed consent

Date of first enrolment
25/06/2010

Date of final enrolment
24/06/2015

Locations

Countries of recruitment
Singapore

Study participating centre

Endoscope Center at the National University Health System
Singapore
-

Sponsor information

Organisation
National Medical Research Council

Sponsor details
The National Medical Research Council (NMRC)
11 Biopolis Way
-
Singapore
138667

Sponsor type
Research council

Website
http://www.nmrc.gov.sg/content/nmrc_internet/home.html

ROR
https://ror.org/04x3cxs03

Organisation
National Research Foundation-Proof-of-Concept

Sponsor details
1 Create Way
#12-02 Create Tower
-
Singapore
138602

Sponsor type
Government

Organisation
Academic Research Fund from Ministry of Education

Sponsor details

1 North Buona Vista Drive
-
Singapore
138675

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
National Medical Research Council

Alternative Name(s)
National Medical Research Council (NMRC) Singapore, NMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Singapore

Funder Name
National Research Foundation-Prime Minister's office, Republic of Singapore

Alternative Name(s)
National Research Foundation-Prime Minister's office, Republic of Singapore, Singapore National Research Foundation, National Research Foundation of Singapore, National Research Foundation, Singapore, National Research Foundation, Singapore (NRF), nrfsg, NRF Singapore, NRF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Singapore

Funder Name
Ministry of Education - Singapore

Alternative Name(s)
Ministry of Education, Ministry of Education (Singapore), MOE Singapore, Ministry of Education, Singapore, MOE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Singapore

Results and Publications

Publication and dissemination plan
1. The diagnostic and predictive accuracy, sensitivity and specificity of Raman spectroscopy for the diagnosis of upper GI lesions will be analyzed and published
2. The diagnosis yield of Raman spectroscopy will be evaluated and compared with the routinely used endoscopic examinations techniques
3. The diagnostic and predictive accuracy, sensitivity and specificity of NIR autofluorescence imaging for the diagnosis of upper GI lesions will be analyzed and published
4. The diagnosis yield of NIR autofluorescence imaging will be evaluated and compared with the routinely used endoscopic examinations techniques
5. The diagnostic and predictive accuracy, sensitivity and specificity of NIR autofluorescence imaging combined with Raman spectroscopy for the diagnosis of upper GI lesions will be analyzed and published
6. The diagnosis yield of NIR autofluorescence imaging combined with Raman spectroscopy will be evaluated and compared with the routinely used endoscopic examinations techniques

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/08/2015	10/07/2023	Yes	No