

# Raman spectroscopy and autofluorescence imaging in gastrointestinal tract

<b>Submission date</b> 17/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/07/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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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2. Associate Professor Zhiwei Huang (scientific)  
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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)**

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**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

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## Sponsor information

### Organisation

National Medical Research Council

### Sponsor details

The National Medical Research Council (NMRC)  
11 Biopolis Way

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Singapore  
138667

### Sponsor type

Research council

### Website

[http://www.nmrc.gov.sg/content/nmrc\\_internet/home.html](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?
<a href="#">Results article</a>		05/08/2015	10/07/2023	Yes	No