Information sheet for patients about
the UK–Japan joint colorectal cancer study

Title of the study:

Formula One Study

UK–Japan Joint Study for Risk Factors of Lymph Node Metastasis in Submucosal Invasive (pT1) Colorectal Cancer

INTRODUCTION

We are now starting a new clinical research study wherein patients treated for colorectal cancer in the past will be included as research subjects.
This information sheet will provide information regarding this study and the rights of the included patients. If you are included in this study, please read this information carefully and approach the investigator for clarification if needed or if you would like additional information.

What is the purpose of the study?

This study is an international, a multicentre, and a retrospective study that will collect clinical data regarding the status of lymph node metastasis to identify the risk factors most useful for colorectal cancer management after local excision via the endoscopic or surgical approach. This study is also expected to identify any differences in macroscopic or microscopic characteristics of pT1 tumours potentially associated with international differences in cancer screening and diagnostic systems between the UK and Japan.

Do I have to participate in the study?

Participation in this study is entirely voluntary, and if you do not wish to participate, please express your will to your hospital doctor or study administrator, as described below. You may do so without having to provide a reason, and you will not lose any benefits to which you would otherwise be entitled.

Who is eligible to participate in the study?

Among patients with colorectal cancer who had been treated with surgical intervention between 2008 and 2013 at the following institutions, those diagnosed as having pathological T1 cancer are eligible to be included in this study. A total of approximately 2000 patients will participate in this study.

Participating institutions

- Akita Red Cross hospital
- Cancer Institute Hospital
- Hiroshima University Hospital
- Iwate Medical University
- National Cancer Centre Central Hospital
- National Cancer Centre Hospital, East
- Niigata University
- Shinko Hospital
- The University of Tokyo
- Tokyo Medical and Dental University
- Tokyo Metropolitan Hiroo Hospital

- National Defense Medical College
- Leeds University

What will happen to me if I participate?

This study is a retrospective observational study that does not involve any extra clinical investigation or treatment. You will be provided standard treatments for colorectal cancer, including postoperative surveillance and postoperative treatment, if you needed.

Your study doctor or data manager at your hospital will enter the following data into a database sheet: patient characteristics (age, gender, and tumour location), treatment related factors (e.g. year and month of surgery and treatment types), conventional pathological characteristics of the tumour including lymph node metastasis, and prognosis. In addition, new pathological parameters and morphometric characteristics will be evaluated in this study. Subjects' names and personal data will remain confidential and will not be disclosed in any way.

These data will be anonymously sent to the study administrator located at the Department of Surgery, National Defence Medical College, Japan. Subjects in this database will be identified by subject number allocated by each participating institution. All data collected for this study will be anonymously stored in a main database and used only for research purposes.

What do I have to do?

Because this study is a retrospective observational study, further time and effort on your part will not be required.

What risks or discomforts may occur if I participate?

Because this study is a retrospective observational study that does not involve extra clinical investigation or treatment, adverse events as a result of participating in this study are not expected.

What are the possible benefits of participating?

You may not receive any direct benefit from participating in this study. However, the information we obtain from this study will extend our existing knowledge and help to determine the optimal treatment for future patients with colorectal cancer.

Will there be any cost to me if I participate?

There will be no cost to you for participating in this study. You will not receive any compensation or incentives.

Can I withdraw or be withdrawn from the study?

Participating in the study is voluntary and you are free to withdraw at any time. If you decide to withdraw, you should immediately inform your doctor at your institution or study administrator. Your doctor will not be upset, you will not be penalised in any way and your future care will not be affected.

Will my participation in this study be confidential?

Records that identify you will be kept confidential and will not be made publicly available.

The information collected during the study will be stored in a computer maintained by the study administrator; however, your name will not be stored. Only your study doctor or data manager at your hospital will know that the information is related to you. Clinical data and pathological specimens in the form of digital slides will be sent to the study administrator for analysis; however, your name will not be included with any data that is sent to the study administrator.

Results of the study may be published in the medical literature and/or presented at a scientific conference, but your identity will not be revealed.

Who is organising and funding the study?

This study is being organised by doctors who are interested in the treatment of colorectal cancer in the UK and Japan. Professor Philip Quirke (Leeds University, UK) and Professor Kenichi Sugihara [President of the Japanese Society for Cancer of the Colon and Rectum (JSCCR)] are the project leaders. This study is a clinician-initiated project, and JSCCR is

funding the study. No pharmaceutical drug companies are involved.

Who has reviewed the study?

This study has been approved by the JSCCR Ethics Committee and investigational review board of each institution.

This study complies with the Declaration of Helsinki (version 2013).

Contacts for further information

If during the course of this study, you have questions regarding the nature of the research or your rights, you should contact one of the following:

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TEL

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