Cancer Research UK and
UCL Cancer Trials Centre

Trial protocol
Electronic copy available on request

EARL TRIAL

Electrocautery **A**blation for the **P**revention of **L**ung Cancer

Trial Sponsor:	University College London
Trial Sponsor reference:	UCL/12/1585
Trial funder:	Cancer Research UK
Funder reference:	CR UK/15/077
Clinicaltrials.gov no:	NCT03870152
REC reference:	19/LO/1299
IRAS ID:	263980
Protocol version no:	4.1
Protocol version date:	15 November 2021

Trial Consent form

(Form to be on hospital/institution headed paper)

Site Name: <<insert site name or site number>>

Patient Study ID: <<insert patient study number>>

CONSENT FORM

Name of Study: **E**lectrocautery **a**blation for the p**r**evention of **L**ung Cancer (the **EARL** trial)

Name of Principal Investigator: <<insert name of Principal investigator>>

IRAS No.: 263980

		Please initial box
1.	I confirm that I have read and understand the information sheet dated 25 March 2021 (version 4.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.	☐
3	I understand that relevant sections of my medical notes, and data collected during the study, may be looked at by individuals from the study sponsor University College London and its representatives, including the Cancer Research UK and UCL Cancer Trials Centre (UCL CTC), NHS Trusts/Health Boards, and by individuals from relevant regulatory authorities. In addition, data collected may also be looked at by individuals from the central laboratory, Lungs for Living at UCL. I understand that this data will be pseudonymised meaning I cannot be directly identified from the information they are provided with. I give permission for these individuals to have access to my data.	☐
4.	I agree to my General Practitioner (GP) being informed of my participation in this study.	☐
5.	I understand that the information collected about me will be shared with other researchers to support other ethically approved research in the	☐

	future. These parties may be in regions outside of the EU where data protection laws have different levels of protection to those in the EU. Before this information is shared, any items that could directly identify me would be removed and a code used to link information.	
7.	I agree to give the following research samples to for use in research related to this study. These samples will be sent to Lungs for Living at UCL: • Nasal brushings – only **UCLH patients / patients in participating hospitals** • Blood samples • Bronchial brushings – only **UCLH patients / patients in participating hospitals** • Additional Bronchial biopsies I agree that any remaining research samples can be stored for use in future ethically and scientifically approved research in the UK or overseas, including genetic studies. This research may involve other academic institutions, private or commercial companies. If this research leads to a new commercial discovery, such as the development of a new treatment or medical test, I understand I will not benefit financially from this.	☐
8.	I agree that researchers may undertake genetic analysis of my samples as part of their research in trying to understand how abnormal cells behave.	☐
10.	I agree for my diagnostic lung tissue samples to be independently reviewed by another histopathologist at my hospital and if necessary transferred to the Royal Brompton pathology department for further review. These slides may contain personal identifiable data, but this will remain confidential and will not be shared with any other party. I understand that the independent pathology review is being carried out in addition to routine clinical care (i.e. for research purposes only) and that I will not be informed of the results of the review. I understand that the results of the histology review will be provided to UCL CTC for use in research related to the study. I understand that this data will be pseudonymised meaning I cannot be directly identified from the information they are provided with.	☐
12.	I agree to take part in the above study.	

Name of Patient	Date	Signature
_____	_____	_____
Name of person taking consent (designated responsible person)	Date	Signature
_____	_____	_____

Trial Patient Information Sheet
Electronic copy available on request

CANCER RESEARCH UK

(INSERT HOSPITAL/INSTITUTION LOGO HERE WITH CRUK LOGO INCLUDED)

PATIENT INFORMATION SHEET

EARL TRIAL

Electrocautery Ablation for the Prevention of Lung Cancer (the EARL trial)

IRAS Number: 263980

We are inviting you to take part in a research study called EARL

We would like to invite you to take part in a study.

Before you decide whether or not to take part, we will go through this Patient Information Sheet with you and answer any questions you may have so that you understand why we are running the study and what it would involve for you.

Please take the time to read the information carefully and talk to others about the study if you wish.

Ask us if there is anything you don't understand or if you would like more information. Take your time to decide whether or not you wish to take part.

You are free to decide if you want to take part in this study. If you choose not to take part, this will not affect the care you receive in any way.

You can decide to stop taking part in the study at any time without giving a reason.

If you decide to take part, we will ask you to sign a form to give your consent to take part in the study.

The first part of the Patient Information Sheet provides you with an overall summary of the study. If you would like to find out more, the summary is followed by more detailed information on the purpose of the study; what will happen if you take part and how the study is being run and managed. A glossary is also provided at the end of the Patient Information Sheet to describe any acronyms or abbreviations used.

Important things that you need to know

Summary of research study

You have been invited to take part in this study because your test results (from a biopsy from your airway or sputum sample) suggest you have some abnormal cells lining the airways of your lungs. In time, groups of these abnormal cells (also called lesions) may develop into cancer. For this reason, they are also termed 'pre-cancerous' lesions. Lesions are classified as low-grade (low-risk) or high-grade (high-risk) based on their risk of becoming cancer.

All patients entering the EARL trial will undergo 'surveillance' of these lesions. 'Surveillance' means regularly monitoring the appearance of these lesions by

Trial Technical handbook
Electronic copy available on request

Technical Handbook for use with Olympus ESG-150 or ERBE 300D

This handbook is to be used as a guidance document for the use of the Electrocautery (EC) equipment in the EARL study and is not an exhaustive list detailing all aspects of the EC equipment, its use, and settings. The manufacturer's manual should also be used in conjunction with this manual when using the EC equipment.

For any queries please contact UCL CTC +44 (0) 20 7679 9105 ctc.earl@ucl.ac.uk and the EARL Clinical Fellow Dr Lukas Kalinke l.kalinke@nhs.net or the PI from UCLH Ricky Thakrar ricky.thakrar@nhs.net

Sponsor: University College London

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Trial Laboratory manual
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LABORATORY MANUAL

FOR THE COLLECTION, PROCESSING, STORING AND SHIPPING OF EARL BIOLOGICAL SAMPLES

Sponsor: University College London

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