ISRCTN14949833 https://doi.org/10.1186/ISRCTN14949833

The AspECT EXceL study aims to continue to follow up the AspECT study participants to see if esomeprazole effectiveness continues or increases long-term and investigate the long-term benefits and risks of using esomeprazole with or without aspirin in reducing the risk of cancer

Submission date 08/12/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/05/2023	**Overall study status** Completed	
Last Edited 01/05/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

Barrett's oesophagus is a condition which affects about 2% of the adult population in the Western world. The condition develops when some of the cells in the lining of the lower part of the food pipe become inflamed and damaged due to frequent gastric acid reflux. In a very small number of Barrett's oesophagus patients, the condition may develop into oesophageal cancer years later.

This study is a non-interventional follow-up extension of the AspECT study. In the AspECT trial, patients with Barrett’s oesophagus were followed up for an average of 9 years to see if using 40 mg/day or 80 mg/day of esomeprazole (a proton pump inhibitor drug) with or without 300 mg /day of aspirin, decreased the rate of all causes of death or the conversion to oesophageal cancer or high-grade dysplasia (pre-cancer and oesophageal adenocarcinoma). The study results showed that using 80 mg/day of esomeprazole significantly reduced the combination of all-cause mortality, high-grade dysplasia and Barret’s adenocarcinoma. In addition, the combination of high-dose PPI with 300 mg/day aspirin appeared to be more effective than either drug used alone.

This is an extension of AspECT which aims to continue to follow up the AspECT participants at about 14 years to see if the effectiveness of aspirin with or without PPI continues or increases long-term and to see if any complications from PPI use occur over a longer period of time. The results from this study may also help to define the best age to start aspirin therapy, the best dose and duration of therapy in cancer prevention in the general population.

Who can participate?
Patients with Barrett's oesophagus who participated in the AspECT study

What does the study involve?
This follow-up will take place in the form of a single data snapshot of AspECT participant health status from when the study closed in 2017 to the present date.

What are the possible benefits and risks of participating?
There are no intended/immediate clinical benefits of taking part in this study. However, it is hoped that the results and information from this follow-up study will help to improve the care and management of Barrett’s oesophagus patients in the UK and beyond and provide more information about effective treatments. There are no study drugs or tests involved in the study and no anticipated clinical risks for participants.

Where is the study run from?
University College London Comprehensive Clinical Trials Unit (UCL CCTU) (UK)

When is the study starting and how long is it expected to run for?
December 2022 to April 2025

Who is funding the study?
Cancer Research UK

Who is the main contact?
cctu.aspect_xl@ucl.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-the-long-term-follow-up-of-people-who-have-taken-aspirin-and-esomeprazole-to-help

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
1006239

Central Portfolio Management System (CPMS)
54878

Protocol serial number
CCTU/2019/340

Study information

Scientific Title
Aspirin Esomeprazole Chemoprevention Trial – EXtension Long-term Clinical Study: a cohort follow-up of a Phase III randomised study of aspirin and esomeprazole chemoprevention in Barrett's metaplasia

Acronym
AspECT EXceL

Study objectives

Oesophageal adenocarcinoma is the sixth most common cause of cancer death worldwide and Barrett's oesophagus is the biggest risk factor. The original AspECT trial aimed to evaluate the efficacy of high-dose esomeprazole proton-pump inhibitor (PPI) and aspirin for improving outcomes in patients with Barrett's oesophagus. The primary composite endpoint in AspECT was time to all-cause mortality, oesophageal adenocarcinoma, or high-grade dysplasia, which was analysed with accelerated failure time modelling adjusted for minimisation factors (age, Barrett's oesophagus length, intestinal metaplasia) in all participants in the intention-to-treat population. We now wish to follow up the same endpoints in AspPECT trial participants in the AspECT EXceL study.

The primary composite endpoint is time to all-cause mortality, oesophageal adenocarcinoma, or high-grade dysplasia, whichever occurs first, between randomisation into AspECT and the single data capture of AspECT EXceL.

1. Effects of combined PPI and aspirin on each of the three components of the primary endpoints separately
2. Time to progression to low-grade dysplasia
3. Death from oesophageal cancer
4. New solid GI tumours
5. COVID-19 related deaths
6. The Charlson Comorbidity Index (CCI)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/05/2023, South Central - Hampshire A Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol , BS1 6PN, United Kingdom; +44 (0)2071048033 /53; hampshirea.rec@hra.nhs.uk), ref: 23/SC/0015

Primary study design
Observational

Study design
Non-interventional long-term follow-up study

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Barrett's oesophagus (BO)

Interventions
AspECT EXceL is a non-interventional, data-collection-only study that involves the long-term follow-up of individuals previously recruited into the AspECT trial.

As part of the original AspECT trial, participants were assigned to receive either:
1. Low-dose oral proton pump inhibitor (PPI) (esomeprazole) and no aspirin
2. High-dose PPI (esomeprazole) and no aspirin
3. Low-dose PPI (esomeprazole) and aspirin
4. High-dose PPI (esomeprazole) and aspirin

There are no further direct patient interventions required. This study aims to capture a single data snapshot of the original AspECT trial participants' medical records to see if aspirin and PPI effectiveness increases long term and to investigate the long-term benefits and risks of using a PPI with or without aspirin in reducing the risk of cancer from the date of the participant's last study visit.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Esomeprazole, aspirin

Primary outcome(s)
The time to all-cause mortality, oesophageal adenocarcinoma, or high-grade dysplasia, whichever occurs first, between randomisation into AspECT and the single data capture of AspECT EXceL. Data will be collected from the participants' medical records from the date of the participant's last visit for the original AspECT Trial to the time the data snapshot is taken for the AspECT ExCEL study. For deceased patients, this will be from their last AspECT study visit to the date of death.

Key secondary outcome(s)
1. Effects of combined PPI and aspirin on each of the three components of the primary endpoints separately
2. Time to progression to low-grade dysplasia
3. Death from oesophageal cancer
4. New solid GI tumours
5. COVID-19 related deaths
6. Quality of life assessed using the Charlson Comorbidity Index (CCI)
Data will be collected from the participants' medical records from the date of the participant's last visit for the original AspECT trial to the time the data snapshot is taken for the AspECT ExCEL study. For deceased patients, this will be from their last AspECT study visit to the date of death.

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Participants recruited to the original AspECT trial
2. AspECT participants who have signed an AspECT-EXceL consent form or have the use of personal data covered by another access agreement
3. Participants who have given consent to allow access to AspECT data or have access covered by another access agreement

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
831

Key exclusion criteria
1. Participants who are alive and unable or unwilling to give consent to participate in AspECT ExceL and whose personal data is not covered by any other data access agreement
2. Participants unwilling to give consent to allow access to AspECT data and are not covered by any other data access agreement
3. Participants not included in the original AspECT trial

Date of first enrolment
01/07/2023

Date of final enrolment
14/10/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Gloucester Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
New Queen Elizabeth II Hospital
Welwyn Garden City
United Kingdom
AL7 4HQ

Study participating centre
Queens Medical Centre
Nottingham University Hospital
Derby Road

Nottingham
United Kingdom
NG7 2UH

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Taunton Hospital
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Queen Margaret Hospital
Whitefield Road
Dunfermline
United Kingdom
KY12 0SU

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
Ulster Hospital
Upper Newtownards Rd
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University College London Comprehensive Clinical Trials Unit (UCL CCTU)

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (Chief Investigator: Prof. Janusz Jankowski, j.jankowski@ucl.ac.uk). Anonymised data will be shared. The results of the study will be published after completing the final statistical analysis within 12 months of study completion. A summary of the AspECT EXceL study protocol will be made available for public access throughout the duration of the study.

At the end of the study and following the publication of the final reports, applications for access to the study dataset will be submitted in writing to UCL CCTU. Access will only be granted after formal consideration by the study's Chief Investigator and the oversight committees.

Appropriate data-sharing agreements will be in place. The results of the trial will be disseminated regardless of the direction of effect. The publication of results will comply with the UCL and UCL CCTU Publication Policies and will include submission to open-access journals.

Types of analyses: All analyses will be performed using the intention-to-treat (ITT) population. All patients will be analysed according to their randomised treatment arm irrespective of whether the treatment (or absence of treatment) was received.

A mediation analysis will be considered as to the effect of trial adherence to randomised treatment, with a focus on changes in the interim period in terms of drugs taken (PPI + aspirin) via a retrospective review of patient notes. Separately, a further analysis using Restricted Mean Survival Time will be used should there be a clear departure from the constant hazard assumption.

Informed consent will be obtained from alive patients who participated in the original AspECT trial and CAG and equivalents approvals will be sought to access the clinical information of deceased patients who participated in the original AspECT trial.

IPD sharing plan summary

Available on request