

# A trial comparing the effectiveness and safety of venetoclax to standard chemotherapy in acute myeloid leukaemia patients

<b>Submission date</b> 08/12/2020	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/07/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-venetoclax-with-low-dose-cytarabine-for-acute-myeloid-leukaemia-victor>

### Background and study aims

Acute myeloid leukaemia (AML) is an aggressive blood cancer affecting 3000+ people per year in the UK. Patients who are relatively young and healthy are given potentially curative treatment with intensive chemotherapy (IC) which is fairly effective in inducing remission, and for some patients, long-term cure. IC has severe short-term side effects including decreasing white blood cell count (which can lead to potentially fatal infections), mouth ulcers, nausea, vomiting and hair loss. Long-term side effects include infertility, heart failure and secondary cancers. Side effects are often more severe in older patients who have pre-existing medical conditions; therefore these patients are given treatments to control (rather than cure) the disease; less than half of these patients survive for over 1 year.

A new treatment (venetoclax) has been tested on patients with AML who were not suitable for IC, and the results have been extremely positive. Patients with a specific type of AML (called NPM1 mutated) had a particularly good response, with over 90% achieving a remission and over 75% alive after 2 years. This result seems as good as, if not better than results achieved with IC. Therefore, we would like to compare venetoclax to IC to see if the outcomes really are comparable.

We will initially test this in patients aged 55+ who are healthy enough to receive IC. We may subsequently lower the age limit if venetoclax is showing to be as good as IC. We will monitor patients throughout treatment and those who are not responding well can switch treatments or receive a stem cell transplant.

If successful, venetoclax treatment may replace IC, which would greatly benefit patient's quality of life both during and after therapy. This study will be open at selected hospitals in the UK, Denmark and New Zealand and will be open for 2 years.

### Who can participate?

Adults aged 55 years or more, diagnosed with acute myeloid leukaemia.

### What does the study involve?

Patients will be given either the new trial treatment (venetoclax combined with low dose cytarabine) or the current standard treatment (intensive chemotherapy) for AML, as this is a randomised study patients will be randomly allocated to receive either treatment. Patients randomised to receive venetoclax will have up to 12 cycles (28-day cycles) of venetoclax and low dose cytarabine, potentially followed by 12 months of venetoclax on its own. Venetoclax is an oral tablet that can be taken at home. Patients randomised to the standard treatment will receive up to 4 cycles of intensive chemotherapy (this is the treatment patients would receive if they did not enter the trial). Patients in both arms will be monitored closely for their response to treatment via regular blood and bone marrow tests (these would be taken during treatment if the patient entered the trial or not). If the doctor feels the patient is not responding as well as expected the treatment will be changed. Patients who enter the trial will be followed up for 2 years.

### What are the possible benefits and risks of participating?

There is no guaranteed benefit to taking part in this study because we do not yet know which of the two treatments is better and it is possible that the new treatment is not as good as the standard treatment. Equally, it is possible that the standard treatment is not as good which is why this study is being done. The careful monitoring you will receive if you take part in this study is a safeguard against this risk. As the new treatment is likely to be less toxic, it is possible that patients receiving this treatment may experience fewer side effects. The information gained from this study will help improve treatment for other people with AML in the future. Risks involved are the usual risks with any of the procedures, such as bone marrow biopsies and blood tests for example experiencing discomfort, bleeding or bruising. These risks would be the same if you enter the trial or not.

### Where is the study run from?

Cancer Research UK Clinical Trials Unit, University of Birmingham (UK)

### When is the study starting and how long is it expected to run for?

October 2020 to December 2028

### Who is funding the study?

Cancer Research UK

### Who is the main contact?

Catherine Thomas, [VICTOR@trials.bham.ac.uk](mailto:VICTOR@trials.bham.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Ms Catherine Thomas

### Contact details

VICTOR Trial Office  
Centre for Clinical Haematology  
Queen Elizabeth Hospital  
Birmingham

United Kingdom  
B15 2TH  
+44 (0)121 371 7861  
victor@trials.bham.ac.uk

## Additional identifiers

### EudraCT/CTIS number

2020-000273-24

### IRAS number

277635

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CPMS 46867, IRAS 277635

## Study information

### Scientific Title

Venetoclax or Intensive Chemotherapy for Treatment Of favourable Risk acute myeloid leukaemia: a molecularly guided phase 2 study

### Acronym

VICTOR

### Study objectives

The aim of this study is to gather more information on the effectiveness and safety of a new treatment (venetoclax combined with low dose cytarabine) compared to the current standard treatment (intensive chemotherapy) for acute myeloid leukaemia

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 01/10/2020, London Bridge REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8019; londonbridge.rec@hra.nhs.uk), ref: 20/LO/1056

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Acute myeloid leukaemia

## **Interventions**

VICTOR is a multicentre trial which will open in the UK, Denmark and New Zealand for patients with Acute Myeloid Leukaemia (AML) with NPM1 mutation. It is a randomised controlled trial and patients will be randomised to receive either standard of care intensive chemotherapy (with cytarabine, daunorubicin and gemtuzumab ozogamicin (DAGO)) or venetoclax combined with cytarabine (VEN+LDAC- the experimental combination). The primary aim of the study is to compare the two treatment arms in terms of molecular event free survival (mEFS), which is defined as failure to achieve complete remission (or complete remission without recovered blood counts) after two cycles of treatment, molecular persistence (the disease is not responding to treatment), progression or relapse resulting in a treatment change (this will be assessed via bone marrow samples), relapse or death. The two treatment arms will also be compared in terms of toxicity (side effects), overall survival, time to response or disease progression, quality of life and resource use (number of transfusions, days in hospital and use of anti-infective medication). The aim is to demonstrate non-inferiority in the experimental arm- therefore to show that this arm is at least equivalent to the current standard of care in terms of treatment outcome. It is expected that this arm will be associated with less severe side effects and economic cost compared to standard chemotherapy. Venetoclax is already widely used in the treatment of other blood cancers such as chronic lymphocytic leukaemia and research studies so far have demonstrated impressive outcomes in AML NPM1 mutated patients who have received venetoclax in combination with another chemotherapy drug- such as cytarabine. This is the first trial directly comparing VEN+LDAC to standard of care chemotherapy (IC) in patients who are fit enough to receive chemotherapy. VICTOR will recruit 156 patients to be randomised 1:1 between the two treatment arms over two years. Patients 60 years and over will be recruited initially as this age group experience the most severe and potentially life threatening side effects of IC. There is the potential to recruit younger patients (lowering the age limit to 50 years), after 12 months of recruitment if it is demonstrated that VEN+LDAC is non-inferior to IC. It is expected that approximately 30 younger patients may be recruited additional to the 156 older patients. This trial will also monitor minimal residual disease (MRD) throughout the trial, via bone marrow samples sent to the laboratory at Guys Hospital. This will be used to inform patient treatment options and may act as a predictor of relapse so patients can be treated accordingly.

## **Interim Analysis**

Interim analyses are planned every 6 months to ensure close monitoring of patients randomised to VEN+LDAC to ensure they are not experiencing inferior treatment compared to IC. It is expected that an estimated 16, 50 and 100 patients will be available for interim analysis at 6, 12 and 18 months respectively. Interim analysis will be reviewed by the independent Data Monitoring Committee (DMC). We expect to see no more than 2-3 events (as defined by primary

outcome mEFS) out of 16 patients (at 6 months), 12-13 events out of 50 patients (at 12 months) and 33-34 events out of 100 patients (at 18 months), which is deemed as the maximum acceptable level of events at those time points. If more events occur, the DMC may consider stopping the trial early for safety. If the 12 months/50 patients interim analysis demonstrates non-inferiority, younger patients (aged 50-59 years) may be recruited into the trial.

Updated 09/02/2024:

Interim analyses are planned every 6 months to ensure close monitoring of patients randomised to VEN+LDAC to ensure they are not experiencing inferior treatment compared to IC. The Data Monitoring Committee will review all outcome data on the two treatment arms. The trial will be adaptive and allow a staged expansion of the population to include younger patients as the evidence emerges of safety and non-inferiority in the older patients. This decision will first be considered at the 18-month interim analysis. If at that point, the interim data show that there are no safety signals to indicate it is unsafe to include younger patients, or that there is sufficient evidence that VEN is truly non-inferior, then the Data Monitoring Committee will consider making recommendations to expand the eligible population to include younger patients in a step-wise manner. Further evaluation may also take place at subsequent interim analyses when more extensive safety and efficacy data is anticipated.

#### Patients, Assessments and Treatment

Patients will be identified via inpatient wards or via multi-disciplinary teams if being referred from another hospital. Patients will be approached by their consultant and other, trained, members of the clinic team to introduce and discuss the trial. Patients will receive a patient information sheet and will be given at least 24 hours to review the information and ask any additional questions they may have.

Patients will attend hospital for screening tests to determine if they are eligible for the trial. A blood sample will be sent to Guys Hospital for molecular testing for the NPM1 mutation (around one third of patients will have this mutation). A separate consent form and information sheet for sample collection is provided. Patients will also have blood and bone marrow tests and a physical exam as part of screening, patients would receive these tests as part of standard care to ensure they are fit for chemotherapy and confirm disease status. Performance status, comprehensive geriatric assessment and quality of life questionnaires will also be performed prior to treatment.

Patients randomised to DAGO (standard of care) will receive 4 cycles of treatment (with at least 2 cycles being an inpatient). Each cycle lasts up to 42 days and the next cycle of treatment can be started once the patient's blood counts have recovered.

Patients randomised to VEN+LDAC will receive up to 12 cycles of treatment with both drugs (with at least 1 cycle being an inpatient), with the potential to receive VEN alone for a further 12 months following this (venetoclax maintenance phase). Each cycle lasts up to 42 days and the next cycle of treatment can be started once the patient's blood counts have recovered.

Patients will be monitored closely and patients in either arm who are not responding to treatment or their disease relapses will have their treatment switched accordingly. Response assessment will be carried out at the end of every cycle for the first 4 cycles, then following 6, 9, 12, 15, 18, 21 and 24 months after being randomised into the trial. Patients randomised to DAGO may switch to receive VEN+LDAC when/if non-inferiority of this arm is demonstrated. For other patients a salvage chemotherapy with stem cell transplant is recommended in the protocol.

Patients will attend hospital (or be an inpatient) for their chemotherapy in both arms during the first 4 cycles for DAGO patients and 12 cycles for VEN+LDAC patients. Post cycle 4 patients will only be seen monthly up to month 12 for trial purposes. Following this patients will be followed up every 3 months until month 24 (including patients on venetoclax maintenance) for trial purposes. During treatment and follow up patients will have blood and bone marrow tests and physical exams to monitor their disease, health and any side effects of treatment. Patients will not experience any additional visits or clinical tests compared to standard of care as a result of taking part in VICTOR. Patients will be asked to complete a quality of life questionnaire pre-treatment and at 3, 6, 12, 18 and 24 months after being entered into the trial. This is a short questionnaire which can be completed at clinic visits. At these time points patients performance status and comprehensive geriatric assessment will also be assessed.

## **Intervention Type**

Drug

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Venetoclax, cytarabine, daunorubicin, gemtuzumab ozogamicin

## **Primary outcome measure**

1. Molecular event-free survival time (mEFS) is calculated as the time from date of randomisation to the date of the first recorded event, where an event is defined as follows:
  - 1.1. Failure to achieve morphological CR or CRi after two cycles of therapy measured using blood and bone marrow tests
    - 1.1.1. Morphological complete remission (CR): <5% blasts in a cellular bone marrow with neutrophil count  $\geq 1 \times 10^9/L$  and platelet count  $\geq 100 \times 10^9/L$
    - 1.1.2. Morphological complete remission with incomplete blood count recovery (CRi): <5% blasts but with neutropenia (neutrophil count  $< 1 \times 10^9/L$ ) or thrombocytopenia (platelet count  $< 100 \times 10^9/L$ )
  - 1.2. Molecular persistence, progression or relapse (i.e. molecular failure) requiring treatment change measured using blood and bone marrow tests
    - 1.2.1. Molecular persistence: Detectable NPM1 mutant transcripts present after completion of treatment, confirmed on a second consecutive sample. For the primary endpoint, molecular persistence is assessed at the end of the fourth cycle of primary treatment in both arms
    - 1.2.2. Molecular relapse: Detectable NPM1 mutant transcripts, confirmed on a second consecutive sample showing an increase of >1 log in a patient who previously tested negative in at least one technically adequate bone marrow sample (i.e. ABL Ct <26.5)
    - 1.2.3. Molecular progression: An increase in NPM1 mutant transcript levels by >1 log, confirmed on a second sample
  - 1.3. Morphological relapse ( $\geq 5\%$  blasts in the blood or bone marrow in a patient with a previously documented CR, CRi or morphological leukaemia free state)
  - 1.4. Death from any cause measured using patient records

## **Secondary outcome measures**

1. Occurrence of morphological complete remission (CR) by the end of the second cycle of treatment is evaluated from the morphological response assessments taken at the end of cycles 1 and 2
2. Death within 30 and 60 days from trial entry will include deaths from any cause and can only

be evaluated in those patients who have been followed up for these periods of time

3. Overall survival time is calculated as the time from date of randomisation to date of death from any cause; patients alive at the time of analysis will be censored at their date last seen alive
4. Time to morphological relapse is calculated as the time from date of complete morphological remission to date when morphological relapse is first recorded
5. Time to molecular relapse is calculated as the time from date of molecular remission to date when molecular relapse is first recorded
6. Cumulative occurrence of grade 3 and 4 adverse events (AE) at 12 and 24 months is evaluated as the total number of grade 3 and 4 AE that are reported during these periods, from all AE that are reported and graded according to CTCAE criteria throughout the duration of the trial
7. Prevalence of molecular complete remission at month 3, 6 and 12 is evaluated from the molecular response assessments taken at these approximate time points from trial entry
8. Cumulative resource use at 12 and 24 months is calculated as total number of hospital admission days, total blood product usage and total number of days on intravenous antibiotics and antifungals that are reported for these periods of time from trial entry
9. Health-related quality of life (QoL) at month 3, 6, 12, 18 and 24 is evaluated from the EORTC QLQ-C30 and EQ-5D questionnaires completed by patients at clinic visits occurring at these approximate time points from trial entry; the questionnaires will yield 15 and 2 different measures of QoL respectively
10. Performance status evaluated by clinical assessment according to the Eastern Cooperative Oncology Group classification (ECOG 0, 1, 2, 3 or 4) during clinic visits occurring at baseline and at month 3, 6, 12, 18 and 24
11. Comprehensive Geriatric Assessment (CGA) comprises multiple measures of frailty that are evaluated during clinic visits at baseline and at month 12 and 24 and include: total number of medications prescribed, Hospital Anxiety and Depression score, Instrumental Activities of Daily Living score, Blessed Orientation Memory Concentration Test score, body mass index, weight, serum albumin level and timed get-up and go measure

### **Overall study start date**

01/10/2020

### **Completion date**

30/12/2028

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 09/02/2024:

1. Diagnosis of CD33-positive acute myeloid leukaemia
2. Age  $\geq 55$  years (prior to the interim analyses performed after enrolment of 50 and 100 patients)
3. Genotype NPM1mut FLT3 ITDneg (FLT3- Tyrosine Kinase Domain mutation, TKD, is permitted)
4. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2
5. Serum creatinine  $\leq 1.5 \times$  ULN (upper limit of normal)
6. Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST)  $\leq 2.5$  ULN and bilirubin  $\leq 2 \times$  ULN
7. Able to provide written informed consent
8. Considered fit for intensive chemotherapy with anthracyclines by treating physician

Previous inclusion criteria:

1. Diagnosis of CD33-positive acute myeloid leukaemia

2. Age  $\geq 60$  years (prior to the interim analyses performed after enrolment of 50 and 100 patients)
3. Genotype NPM1mut FLT3 ITDneg (FLT3- Tyrosine Kinase Domain mutation, TKD, is permitted)
4. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2
5. Serum creatinine  $\leq 1.5 \times$  ULN (upper limit of normal)
6. Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST)  $\leq 2.5$  ULN and bilirubin  $\leq 2 \times$  ULN
7. Able to provide written informed consent
8. Considered fit for intensive chemotherapy with anthracyclines by treating physician

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

55 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 156; UK Sample Size: 143

### **Key exclusion criteria**

1. Previous chemotherapy for AML or any antecedent haematological condition, with the exception of hydroxycarbamide to control white blood cell count
2. Other active malignancy requiring treatment
3. Newly diagnosed or uncontrolled HIV or hepatitis B or C infection. Patients with known chronic infections may enrol if the last two tests for viral load have been negative and their current therapy does not include a protease inhibitor or a non-nucleoside reverse-transcriptase inhibitor
4. Pregnant and lactating patients (patients of childbearing potential must have a negative pregnancy test prior to study entry)
5. Females of childbearing potential, and their partners, not willing to use adequate contraception during and for up to 6 months after treatment
6. Unable to swallow tablets whole
7. Known hypersensitivity to any of the IMPs
8. Patients known to require vaccination with a live vaccine during the treatment period

### **Date of first enrolment**

01/03/2021

### **Date of final enrolment**

01/06/2026

## **Locations**

### **Countries of recruitment**



England

Northern Ireland

Scotland

United Kingdom

Wales

**Study participating centre**

**John Radcliffe Hospital**

Oxford University Hospitals NHS Foundation Trust

Headley Way

Oxford

United Kingdom

OX3 9DU

**Study participating centre**

**Central Manchester University Hospitals NHS Foundation Trust**

Cobbett House

Oxford Road

Manchester

United Kingdom

M13 9WL

**Study participating centre**

**Victoria Hospital**

Blackpool Teaching Hospitals NHS Foundation Trust

Whinney Heys Road

Blackpool

United Kingdom

FY3 8NR

**Study participating centre**

**Guy's Hospital**

Guy's & St Thomas' NHS Foundation Trust

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre**

**Queens Hospital**

Barking, Havering and Redbridge University Hospitals NHS Trust

Rom Valley Way

Romford

United Kingdom

RM7 0AG

**Study participating centre**

**The Royal London Hospital**

Barts Health NHS Trust

Whitechapel Road

Whitechapel

London

United Kingdom

E1 1BB

**Study participating centre**

**University College London Hospital**

University College London Hospitals NHS Foundation Trust

250 Euston Road

London

United Kingdom

NW1 2PG

**Study participating centre**

**Queen Elizabeth Hospital Birmingham**

University Hospitals Birmingham NHS Foundation Trust

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2TH

**Study participating centre**

**St. Mary's Hospital**

Imperial College Healthcare NHS Trust

Praed Street

London

United Kingdom

W2 1NY

**Study participating centre**

**The Royal Marsden Hospital**

The Royal Marsden NHS Foundation Trust  
Fulham Road  
Chelsea  
London  
United Kingdom  
SW3 6JJ

**Study participating centre**

**Belfast City Hospital**

Belfast Health & Social Care Trust  
51 Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

**Study participating centre**

**Bristol Royal Infirmary**

University Hospitals Bristol and Weston NHS Foundation Trust  
Marlborough Street  
Bristol  
United Kingdom  
BS1 3NU

**Study participating centre**

**Royal Stoke University Hospital**

University Hospitals of North Midlands NHS Trust  
Newcastle Road  
Stoke-on-Trent  
United Kingdom  
ST4 6QG

**Study participating centre**

**Southampton General Hospital**

University of Southampton and University Hospital Southampton NHS Foundation Trust  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**  
**Gartnavel Royal Hospital**  
NHS Greater Glasgow and Clyde  
1055 Great Western Road  
Glasgow  
United Kingdom  
G12 0XH

**Study participating centre**  
**The Christie Hospital**  
The Christie NHS Foundation Trust  
550 Wilmslow Road  
Withington  
Manchester  
United Kingdom  
M20 4BX

**Study participating centre**  
**Cardiff & Vale University LHB**  
Corporate Head Quarters  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**  
**Worcestershire Royal Hospital**  
Worcestershire Acute Hospitals NHS Trust  
Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1DD

**Study participating centre**  
**Queens Medical Centre**  
Nottingham University Hospitals NHS Trust  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**Freeman Hospital**

The Newcastle upon Tyne Hospitals NHS Foundation Trust  
Freeman Road  
High Heaton  
Newcastle-Upon-Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**

**NHS Grampian**

Summerfield House  
2 Eday Road  
Aberdeen  
United Kingdom  
AB15 6RE

**Study participating centre**

**St. James's University Hospital**

Leeds Teaching Hospitals NHS Trust  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**

**NHS Lothian**

Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
United Kingdom  
EH1 3EG

**Study participating centre**

**Leicester Royal Infirmary**

University Hospitals of Leicester NHS Trust  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**Swansea Bay University Local Health Board**  
One Talbot Gateway  
Seaway Drive  
Seaway Parade Industrial Estate  
Baglan  
Port Talbot  
United Kingdom  
SA12 7BR

**Study participating centre**  
**Norfolk and Norwich University Hospitals NHS Foundation Trust**  
Colney Lane  
Colney  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**  
**Northern General Hospital**  
Sheffield Teaching Hospitals NHS Foundation Trust  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**  
**Salford Royal Hospital**  
Salford Royal NHS Foundation Trust  
Stott Lane  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**  
**Hull Royal Infirmary**  
Hull University Teaching Hospitals NHS Trust  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**

**Bradford Royal Infirmary**

Bradford Teaching Hospitals NHS Foundation Trust  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**

**King's College Hospital**

King's College Hospital NHS Foundation Trust  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**

**Royal Derby Hospital**

University Hospitals of Derby and Burton NHS Foundation Trust  
Uttoxeter Road  
Derby  
United Kingdom  
DE22 3NE

**Study participating centre**

**St George's Hospital**

St George's University Hospitals NHS Foundation Trust  
Blackshaw Road  
Tooting  
London  
United Kingdom  
SW17 0QT

**Study participating centre**

**Royal Devon & Exeter Hospital**

Royal Devon and Exeter NHS Foundation Trust  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**  
**Colchester District General Hospital**  
East Suffolk and North Essex NHS Foundation Trust  
Turner Road  
Colchester  
United Kingdom  
CO4 5JL

**Study participating centre**  
**North Manchester General Hospital**  
Pennine Acute Hospitals NHS Trust  
Delaunays Road  
Crumpsall  
Manchester  
United Kingdom  
M8 5RB

**Study participating centre**  
**Worthing Hospital**  
Western Sussex Hospitals NHS Foundation Trust  
Lyndhurst Road  
Worthing  
United Kingdom  
BN11 2DH

**Study participating centre**  
**Betsi Cadwaladr University LHB**  
Executive Offices  
Ysbyty  
Gwynedd  
Penrhosgarnedd  
Bangor  
United Kingdom  
LL57 2PW

**Study participating centre**  
**Walsgrave General Hospital**  
University Hospitals Coventry and Warwickshire NHS Trust  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX



**Study participating centre**

**Clatterbridge Hospital**

The Clatterbridge Cancer Centre NHS Foundation Trust  
Clatterbridge Road  
Bebington  
Wirral  
United Kingdom  
CH63 4JY

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Cambridge Biomedical Campus  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**

**South Tees Hospitals NHS Foundation Trust**

James Cook University Hospital  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**

**Salisbury NHS Foundation Trust**

Salisbury District Hospital  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre**

**Royal Oldham Hospital**

Royal Oldham Hospital  
Rochdale Road  
Oldham  
United Kingdom  
OL1 2JH

# Sponsor information

## Organisation

University of Birmingham

## Sponsor details

Research Support Group  
Aston Webb Building Room 119  
Edgbaston  
Birmingham  
England  
United Kingdom  
B15 2TT  
+44 (0)121 4142644  
researchgovernance@contacts.bham.ac.uk

## Sponsor type

University/education

## Website

<http://www.birmingham.ac.uk/index.aspx>

## ROR

<https://ror.org/03angcq70>

# Funder(s)

## Funder type

Charity

## Funder Name

Cancer Research UK; Grant Codes: C65869/A29806

## Alternative Name(s)

CR\_UK, Cancer Research UK - London, CRUK

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

30/12/2029

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the trial management group following the end of trial closure currently expected to be July 2026. Requests will be considered on an individual basis by contacting victor@trials.bham.ac.uk

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		14/11/2022	23/11/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No