

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

Submission date 08/12/2020	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/12/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/07/2025	Condition category 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

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

Clinical Trials Information System (CTIS)
2020-000273-24

Integrated Research Application System (IRAS)
277635

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)

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

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 ≥ 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) ≤ 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 ≥ 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) ≤ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

55 years

Sex

All

Key exclusion criteria

1. Previous chemotherapy for AML or any antedecent 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**

United Kingdom

England

Northern Ireland

Scotland

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

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, 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 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?
Protocol article	Participant information sheet	14/11/2022	23/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes