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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/12/2020	**Overall study status** Ongoing	
Last Edited 30/07/2025	**Condition category** Cancer	

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

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Additional identifiers

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

Integrated Research Application System (IRAS)
277635

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, cyatarbine, 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 ≥1x109/L and platelet count ≥100 x 10(9)L
1.1.2.Morphological complete remission with incomplete blood count recovery (CRi): <5% blasts but with neutropenia (neutrophil count <1x10(9)/L) or thrombocytopenia (platelet count <100 x 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 (≥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 <=1.5 x ULN (upper limit of normal)
6. Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) <=2.5 ULN and bilirubin <=2 x 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 <=1.5 x ULN (upper limit of normal)
6. Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) <=2.5 ULN and bilirubin <=2 x 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 Hopsital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Oxford
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OX3 9DU

Study participating centre
Central Manchester University Hospitals NHS Foundation Trust
Cobbett House
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M13 9WL

Study participating centre
Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
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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
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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
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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
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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
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BT9 7AB

Study participating centre
Bristol Royal Infirmary
University Hospitals Bristol and Weston NHS Foudnation Trust
Marlborough Street
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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
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SO16 6YD

Study participating centre
Gartnavel Royal Hospital
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The Christie Hospital
The Christie NHS Foundation Trust
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M20 4BX

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Charles Hastings Way
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NE7 7DN

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LS9 7TF

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SE5 9RS

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DE22 3NE

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St George's Hospital
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Royal Devon and Exeter NHS Foundation Trust
Barrack Road
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EX2 5DW

Study participating centre
Colchester District General Hospital
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Turner Road
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CO4 5JL

Study participating centre
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M8 5RB

Study participating centre
Worthing Hospital
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Lyndhurst Road
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Penrhosgarnedd
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United Kingdom
LL57 2PW

Study participating centre
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Study participating centre
Clatterbridge Hospital
The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Road
Bebington
Wirral
United Kingdom
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Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
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Study participating centre
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Study participating centre
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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		14/11/2022	23/11/2022	Yes	No
HRA research summary			28/06/2023	No	No