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Chart review assessing venetoclax treatment outcomes for AML - AML Real World Evidence Initiative (ARC)

Submission date
29/09/2023

Recruitment status
No longer recruiting

Registration date
10/11/2023

Overall study status
Completed

Last Edited
20/08/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study investigates venetoclax use in the treatment of acute myeloid leukaemia (AML) in Great Britain (GB). Venetoclax is a treatment for AML that was recently approved in GB. Venetoclax is given as a combination with other medications, with different combinations available, for AML patients who have never received a previous treatment and who cannot receive intensive chemotherapy. Clinical trials have shown venetoclax works well compared to other medications, but currently, there is limited information on how it works in everyday clinics. This study will help provide information on how this treatment is used in the real world. The study aims to describe how well this treatment works, including survival, the time the treatment continues to work for the patient, how often patients have to visit their doctor or hospital when taking the treatment, and how different treatment combinations are used in GB overall.

Who can participate?
Adult patients with AML aged 18 years or older at AML diagnosis who are taking a venetoclax combination treatment (for at least 28 days) because they cannot receive chemotherapy

What does the study involve?
This multi-centre study will be run across eight to nine sites. Doctors will review medical records for AML patients treated with different venetoclax combinations and enter patient information into an online form. Patients themselves are not directly involved, and there will be no changes to their care.

Patient demographics (e.g. age, sex), clinical characteristics (e.g. other diseases or medical conditions a patient has at the time), treatment patterns (e.g. when the treatment was taken and how much was taken), effectiveness (how well the medicine works including survival), and how often patients visit their doctor or hospital whilst taking the treatment will be collected. Information that cannot reveal the patient's identity will be collected, and this will be anonymised in the final database.

What are the possible benefits and risks of participating?
Patients will not directly participate in this study but their medical records will be reviewed by hospital staff, who will identify which records are eligible for the study. Waiver for Informed Consent has been granted by HRA, as no personal or sensitive data is collected as part of this research. Any medical record data collected will be pseudonymised.

Where is the study run from?
AbbVie (UK)

When is the study starting and how long is it expected to run for?
November 2022 to May 2024

Who is funding the study?
AbbVie Inc (US)

Who is the main contact?
Abbvie UK Medical Information, ukmedinfo@abbvie.com

Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
326050

Central Portfolio Management System (CPMS)
55421

Protocol serial number
H18.Oncology12-SR1812

Study information

Scientific Title
A centre-based chart review study to assess treatment outcomes of venetoclax for the treatment of acute myeloid leukemia (AML)

Study objectives
To describe the real world outcomes and treatment patterns in newly diagnosed AML patients who are ineligible for intensive chemotherapy receiving venetoclax-based combinations in Great Britain

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 13/04/2023, HRA (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)207 104 8000; approvals@hra.nhs.uk), ref: 23/PR/0342

2. Approved 13/04/2023, Health and Care Research Wales (HCRW) (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)207 104 8000; HCRW. approvals@wales.nhs.uk), ref: 23/PR/0342

Primary study design
Observational

Study design
Non-interventional retrospective multicentre cohort study

Study type(s)
Other, Efficacy

Health condition(s) or problem(s) studied
Acute myeloid leukaemia

Interventions

Patients receiving venetoclax combination therapies for their acute myeloid leukaemia (AML) will be eligible for inclusion in the study, as per the inclusion criteria. This study is retrospective in design and so patients will not be consented to participate, instead under the NHS guidance, their data will be accessed by their direct care team only. Once a patient has been identified for inclusion, they will be enrolled and their data will be accessed and entered into the electronic data capture (EDC) system. As the study is retrospective, the patients will not be followed up for any prespecified amount of time. The observation period for the study is from diagnosis of AML up to the most recently available data at the time of data entry. Their data will simply be entered into the EDC and once all data has been entered for each patient, and all data queries have been answered, the study will close.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Venetoclax

Primary outcome(s)
1. Overall survival (OS) will be measured as the number of days between the initiation of the studied line of therapy (i.e., venetoclax-based regimen) until death (event) or end of follow-up (censoring).
2. Event-free survival (EFS) will be measured as the number of days between initiating the studied line of therapy and disease progression, refractory disease, or death; both outcomes will be censored at the end of follow-up.

Key secondary outcome(s)
1. AML healthcare resource utilisation (HRU) measured using data entered into the electronic data capture (EDC) system at one timepoint
2. AML treatment patterns for the venetoclax cohort measured using data entered into the electronic data capture (EDC) system at one timepoint

Completion date
06/05/2024

Eligibility

Key inclusion criteria
1. The patient received a diagnosis for AML, if available, suggested diagnosis codes: ICD-9 205.0x or ICD-10 C92.0x, C92.4x, C92.5x
2. The patient was at least 18 years old at AML diagnosis date
3. The patient was initiated on the studied line of therapy (see Table 1 for the list of eligible treatments included based on NCCN guidelines and clinical input) for previously untreated AML:
3.1. Venetoclax in combination with an HMA (on or after 28th May 2021) or LDAC (on or after 25th February 2022), the date of MHRA approvals of venetoclax (for the treatment of adult patients with newly diagnosed AML who are ineligible for intensive chemotherapy)
4. The patient was treated with the studied line of therapy at least 28 days prior to the date of data collection

5. Information on the patient's treatments, selected (or important) clinical characteristics, and outcomes is available from the start of the studied line of therapy onwards

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
168

Key exclusion criteria
1. The patient received the studied line of therapy as part of a clinical trial
2. The patient received prior lines of therapy for AML
3. The patient has a history of malignancies within 2 years prior to the studied line of therapy, other than AML, and with the exception of:
3.1. Myelodysplastic syndromes (MDS), myeloproliferative neoplasm (MPN) or chronic myelomonocytic leukemia (CMML)
3.2. Adequately treated in situ carcinoma of the cervix uteri or carcinoma in situ of the breast
3.3. Basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin
3.4. Previous malignancy confined and surgically resected (or treated with other modalities) with curative intent

Date of first enrolment
31/10/2023

Date of final enrolment
08/04/2024

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford
United Kingdom
OX3 7LE

Study participating centre
University Hospital Wales, Cardiff
Cardiff
United Kingdom
CF14 4XW

Study participating centre
St James University Hospital, Leeds
Leeds
United Kingdom
LS9 7TF

Study participating centre
Northwick Park Hospital
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Nottingham University Hospital
Nottingham
United Kingdom
NG7 2UH

Study participating centre
University Hospitals Birmingham
Birmingham
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B15 2GW

Study participating centre

University College London Hospital
London
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NW1 2BU

Study participating centre
Queen Alexandra Hospital, Portsmouth
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United Kingdom
PO6 3LY

Study participating centre
Royal Hallamshire Hospital, Sheffield
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United Kingdom
S10 2JF

Sponsor information

Organisation
AbbVie (United Kingdom)

ROR
https://ror.org/04tnbfn25

Funder(s)

Funder type
Industry

Funder Name
AbbVie

Alternative Name(s)
AbbVie Inc., AbbVie U.S., AbbVie US, Allergan

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
For data privacy reasons, there are no plans to share individual patient level data (IPD). AbbVie will only have access to summary data tables.

IPD sharing plan summary
Not expected to be made available