ISRCTN68224706 https://doi.org/10.1186/ISRCTN68224706

5-Azacitidine versus 5-Azacitidine in combination with Vorinostat in patients with relapsed acute myeloid leukaemia ineligible for intensive chemotherapy

Submission date
29/06/2012

Recruitment status
No longer recruiting

Registration date
29/06/2012

Overall study status
Completed

Last Edited
19/05/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-azacitidine-with-or-without-vorinostat-for-aml-that-has-come-back-ravva

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-005207-32

ClinicalTrials.gov (NCT)
NCT01617226

Protocol serial number
12452

Study information

Scientific Title
Phase II randomised trial of 5-Azacitidine versus 5-Azacitidine in combination with Vorinostat in patients with relapsed acute myeloid leukaemia ineligible for intensive chemotherapy

Acronym
RAvVA

Study objectives
This is a multicentre, open-label randomised phase II trial, comparing azacitidine monotherapy with combined azacitidine and vorinostat in patients with relapsed Acute Myeloid Leukaemia (AML).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES West Midlands Research Ethics Committee, 12/WM/0087; First MREC approval date 21/05 /2012

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Haematological Oncology; Disease: Leukaemia (acute myeloid)

Interventions
Patients will be randomised on 1:1 ratio to treatment. It is anticipated 80 patients will be randomised to receive azacitidine monotherapy and 80 patients will be randomised to receive azacitidine and vorinostat, combined therapy.

Azacitidine, azacitidine (75 mg/m2) subcutaneous (s.c.) x 7 per cycle on days 1-5, 8, 9 of each 28-day cycle

Azacitidine + vorinostat:
Azacitidine (75 mg/m2) s.c. x 7 per cycle on days 1-5, 8, 9 of each 28-day cycle
Vorinostat (300mg) twice a day (bid) x 7 per cycle on days 3-9 of each 28-day cycle

Follow Up Length: 24 month(s)

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
5-Azacitidine, Vorinostat

Primary outcome(s)
Overall Response Rate assessed within 6 cycles of treatment

Key secondary outcome(s))
Overall Survival from randomisation until 24 months

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Adults with AML in first relapse (except Acute Promyelocytic Leukaemia (APL) as defined by the World Health Organisation (WHO) Classification) who are deemed ineligible for intensive chemotherapy on the grounds of age or co-morbidities
2. Patients must have achieved a previous morphological complete response (CR) as defined by Cheson criteria after treatment with conventional myelosuppressive chemotherapy e.g. anthracycline, araC, etoposide containing regimens
3. Patients are able to receive treatment as an outpatient
4. Adequate renal and hepatic function
5. Patients have given written informed consent
6. Eastern Cooperative Oncology Group (ECOG) performance status <=2
7. Male & Female; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Patients with greater than class III of the New York Heart Association (NYHA) cardiac impairment
2. Blastic transformation of Chronic Myeloid Leukaemia (CML)
3. Any concurrent active malignancy
4. Prior allogeneic/autologous haematopoietic stem cell transplant (HSCT)
5. Pregnant or lactating women (women of childbearing potential must have a negative urine or serum pregnancy test within 7 days prior to the start of treatment)
6. Adults of reproductive potential not willing to use appropriate medically approved contraception during the trial and for specified amount of time afterwards.
7. Patients who have received prior HDAC inhibitor-like treatment as anti-tumour therapy. (Patients who have received HDACi treatment for other indications e.g valproic acid for epilepsy may enrol after a 30-day washout period).
8. Previous anti-tumour therapies, including prior experimental agents or approved anti-tumour small molecules and biologics, within 30 days before
9. Patients who have received prior treatment with demethylating agents such as 5azacitidine or decitabine
10. Patients with contraindications to receiving azacitidine or vorinostat such as hypersenstivity or patients unable to receive subcutaneous injection
11. Active symptomatic fungal, bacterial, and/or viral infection including known active HIV or known viral (A, B, or C) hepatitis
12. Any co-morbidity that could limit compliance with the trial

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Leukaemia and Lymphoma Research

Alternative Name(s)

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		11/01/2022	19/05/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes