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A phase II study of 5-azacitidine in chronic myelomonocytic leukaemia (CMML)

Submission date 26/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 18/12/2008	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/03/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-azacitidine-for-chronic-myelomonocytic-leukaemia-cmml201

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01235117

Protocol serial number
HM08/8540

Study information

Scientific Title

5-azacitidine in chronic myelomonocytic leukaemia (CMML): a two stage phase II, non-randomised, single arm, multi-centre, prospective trial

Acronym
CMML201

Study objectives
To assess the safety, tolerability and efficacy of 5-azacitidine in patients with chronic myelomonocytic leukaemia (CMML).

Please note as of 04/11/2009 this record was updated to include extensions to the anticipated start and end dates; the initial trials dates at the time of registration were:
Initial anticipated start date: 15/03/2009
Initial anticipated end date: 15/03/2011

05/03/2013: Please note that as of 17/08/2010, recruitment for this trial closed

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 04/11/2009:
Northern and Yorkshire Research Ethics Committee on 28/04/2009 (ref: 09/H0903/13)
Amendment 1 on 02/09/2009

Study design
Two stage phase II non-randomised single arm multi-centre prospective trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic myelomonocytic leukaemia

Interventions
Patients should be assessed for their suitability for treatment on Day -5 to Day 1 (start of treatment) of each cycle. Patients should be pre-medicated with ondansentron as per local anti-emetic policy. All patients will receive 100 mg/m^2 of 5-azacitidine on days 1 - 5 by subcutaneous injection. Those patients unable to tolerate the subcutaneous route of drug administration (due to severe local skin reactions) will be withdrawn from the study.

The cycle is repeated every 28 days for at least 6 cycles or until disease progression. After the 6th cycle of treatment all patients will undergo an assessment of response; responders may continue drug administration until loss of response or development of unacceptable toxicity.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
5-azacitidine, ondansentron

Primary outcome(s)
1. To assess the safety and tolerability of 5-azacitidine, monitored throughout the trial
2. To assess the overall response rate, measured at the end of treatment

Key secondary outcome(s))
To assess response of disease to 5-azacitidine, specifically:
1. Incidence of complete remission (CR)/partial remission(PR)
2. Haematological improvement
3. Control of myeloproliferation
4. Incidence of reduction in spleen size by greater than 50%
5. Overall survival
6. Time to acute myeloid leukaemia (AML) transformation of CMML
7. Time to death or AML transformation of CMML
8. Biological correlates

All monitored throughout the trial.

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Patients with newly diagnosed or previously treated CMML-1 or CMML-2 according to World Health Organization (WHO) criteria (2008)
2. Subject is able and willing to sign the informed consent form
3. Age 18 years or over, either sex, at the time of signing the informed consent form
4. WHO performance status of less than or equal to 2 at study entry
5. Women of childbearing potential (WCBP) must have a negative serum or urine pregnancy test within 7 days prior to start of study drug
6. WCBP and men with WCBP partners must agree to use adequate contraceptive methods while on study drug and 6 months after the end of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. CMML with eosinophilia and 5q33 abnormality
2. Previous chemotherapy for CMML except hydroxycarbamide
3. Creatinine concentration more than 1.5 x the institutional upper limit of the normal range
4. Pregnant or lactating females
5. Use of any other experimental drug or therapy within 28 days of baseline
6. Known hypersensitivity to azacitidine
7. Other active malignant disease
8. Known positive for human immunodeficiency virus (HIV) or infectious hepatitis, type B or C
9. Active infection

Date of first enrolment
23/11/2009

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bexley Wing 3rd Floor
Leeds
United Kingdom
LS9 7DF

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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

Funder Name
Celgene Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	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		14/08/2014	29/03/2022	No	Yes