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Intensive compared with nonintensive chemotherapy in treating older patients with acute myeloid leukaemia or myelodysplastic syndrome

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof AK Burnett

Contact details
Department of Haematology
University of Wales College of Medicine
Heath Park
Cardiff
United Kingdom
CF14 4XN
+44 (0)29 2074 2375
burnettak@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00005823

Secondary identifying numbers
LRF AML14

Study information

Scientific Title
A randomised trial for patients with acute myeloid leukaemia (AML) or high-risk myelodysplastic syndrome aged 60 or over

Acronym
AML 14

Study objectives
As of 10/12/2009 this record was updated; all details can be found under the relevant section under the above update date.

Added as of 10/12/2009:
Drugs used in chemotherapy use different ways to stop cancer cells from dividing so they stop growing or die. It is not yet known if stronger doses of chemotherapy given over a longer period of time are as well tolerated or as effective as less intensive chemotherapy.

This randomised phase III trial is studying intensive regimens of chemotherapy to see how well they work compared to nonintensive regimens of chemotherapy in treating older patients with acute myeloid leukemia or myelodysplastic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol was reviewed by the Clinical Trial Advisory Panel of the Leukaemia Research Fund and was approved by the Wales Multicentre Ethics Committee as well as each institution's ethical committee.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute myeloid leukaemia or high-risk myelodysplastic syndrome

Interventions
Patients will be randomised between intensive and non-intensive chemotherapy at diagnosis.

Those in the intensive treatment arm will be randomised between 50 mg/m^2/day daunorubicin versus 35 mg/m^2/day daunorubicin and 200 mg/m^2/day Ara-C versus 400 mg/m^2/day. Patients in the lower dose daunorubicin arm will be further randomised between PSC833 versus control, i.e., no PSC833. After three courses of treatment, patients in the intensive arm will be randomised between short (three courses) versus long (four courses) consolidation therapy.

Patients in the non-intensive arm will be randomised between hydroxyurea and low-dose Ara-C and 45 mg/m^2/day All-trans retinoic acid versus no retinoic acid.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome measure
Added as of 10/12/2009:
1. Survival
2. Response achievement
3. Response duration

Secondary outcome measures
Added as of 10/12/2009:
1. Toxicity by WHO Toxicity Grading after each treatment course
2. Quality of life EORTC QLQ-C30 at 3 days, 1 month, 3 months, and 6 months from study entry
3. Resource use (use of blood products, antibiotics and days in hospital) after each treatment course

Overall study start date
01/12/1998

Completion date
01/11/2003

Eligibility

Key inclusion criteria
Patients are eligible for AML 14 if:
1. They have one of the forms of acute myeloid leukaemia (this can be any type of the de novo or

secondary AML, except acute promyelocytic leukaemia) or myelodysplastic syndrome (refractory anemia with excess blasts [RAEB], refractory anemia with excess blasts in transformation [RAEB-t], chronic myelomonocytic leukemia [CMML]) with more than 10% myeloblasts in the bone marrow
2. They should normally be aged 60 or over, but patients under this age are eligible if the more intensive therapy employed in the current trial for younger patients with AML is not considered a suitable option
3. They have given informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
217 (added as of 02/01/2009)

Key exclusion criteria
Added as of 10/12/2009:
1. Previously received cytotoxic chemotherapy for leukaemia
2. Acute promyelocytic leukaemia
3. In blast transformation of chronic myeloid leukaemia
4. Concurrent active malignancy
5. Patients with liver function test elevation greater than twice normal cannot receive Gemtuzumab Ozogamicin (Mylotarg) and are therefore not eligible for the non-intensive randomisation

Date of first enrolment
01/12/1998

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Haematology
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Leukaemia Research Fund (UK)

Sponsor details
43 Great Ormond Street
London
United Kingdom
WC1N 3JJ

Sponsor type
Charity

Website
http://dspace.dial.pipex.com/lrf-//

ROR
https://ror.org/0055acf80

Funder(s)

Funder type
Charity

Funder Name
Leukaemia Research Fund (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	15/03/2007		Yes	No