ISRCTN65684689 https://doi.org/10.1186/ISRCTN65684689

A randomised trial comparing Z-DEX with VAD as induction therapy for patients with multiple myeloma

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 07/06/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00006232

Secondary identifying numbers
H31

Study information

Scientific Title

Study objectives
Added 07/08/09:
Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. It is not yet known which combination chemotherapy regimen is more effective for multiple myeloma.The aim of this trial is to compare two combination chemotherapy regimens, Zevedos® and dexamethasone (Z-DEX) and vincristine, adriamycin and dexamehasone (VAD) to see how well they work in treating patients with stage II or stage III multiple myeloma.

As of 07/08/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Multicentre randomised active controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Plasma cell neoplasms

Interventions
Z-DEX Regimen: Zovedos capsules Days 1-4. Dexamethasone Days 1-4 (Cycle 1 only: days 8-11). Cycle repeated every 21 days for a max of six cycles.

VAD Regimen: Adriamycin Days 1-4. Vincristine Days 1-4. Dexamethasone Days 1-4 (Cycle 1 only: Days 8-11). Every 21 days for a max of six cycles.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Idarubicin (Zovedos®), dexamethasone, vincristine, doxorubicin (Adriamycin®)

Primary outcome measure
Added 07/08/09:
Response rate

Secondary outcome measures
Added 07/08/09:
1. Time to maximum response
2. Duration of response

Overall study start date
18/10/1996

Completion date
19/03/2002

Eligibility

Key inclusion criteria
Current information as of 07/08/09:
1. Diagnosis of multiple myeloma as in current MRC UK guidelines
2. Durie-Salmon stage II and III disease
3. <75 years of age
4. Bilirubin ≤ 2.34mg/dL
5. Adequate contraceptive measures

Initial information at time of registration:
1. Diagnosis of multiple myeloma as in current MRC UK guidelines
2. Durie-Salmon stage II and III disease

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Added as of 04/10/2007: 200

Key exclusion criteria
Current information as of 07/08/09:
1. Previous or concurrent therapy (except radiotherapy for bone lesions)
2. End stage renal failure (creatinine greater than 5.65 mg/dL after rehydration)
3. Requires dialysis
4. Pregnant or nursing
5. Prior malignancy
6. Other medical condition that would preclude intensive treatment

Initial information at time of registration:
Previous treatment other than local radiotherapy to bone lesions

Date of first enrolment
18/10/1996

Date of final enrolment
19/03/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Pharmacia and Upjohn (UK)

Sponsor details
-
-
United Kingdom
-

Sponsor type
Industry

ROR
https://ror.org/04x4v8p40

Funder(s)

Funder type
Industry

Funder Name
Pharmacia and Upjohn (UK)

Funder Name
Chugai Pharma UK (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?
Results article	results	01/09/2004		Yes	No