

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/06/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00006232

Protocol serial number

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, Zovedos® and dexamethasone (Z-DEX) and vincristine, adriamycin and dexamethasone (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

Study type(s)

Treatment

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(s)

Added 07/08/09:

Response rate

Key secondary outcome(s)

Added 07/08/09:

1. Time to maximum response
2. Duration of response

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 \leq 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Pharmacia and Upjohn (UK)

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

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