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A randomised phase III study on the effect of thalidomide combined with Adriamycin®, dexamethasone and high dose melphalan in patients with multiple myeloma

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 03/10/2016	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00028886

Protocol serial number
HO50

Study information

Scientific Title
A randomised phase III study on the effect of thalidomide combined with Adriamycin®, dexamethasone and high dose melphalan in patients with multiple myeloma

Acronym
HOVON 50 MM/GMMG-HD3

Study objectives
Study objectives:
Evaluation of the effect of thalidomide in addition to Adriamycin, Dexamethasone (AD) and high dose melphalan.

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre randomised active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple myeloma

Interventions
Patients with multiple myeloma, meeting all eligibility criteria will be randomised on entry between:
Arm A: Standard Vincristine, Adriamycin and Dexamethasone (VAD) induction, followed by intensive chemotherapy with High-dose Melphalan, followed by maintenance therapy with alpha-interferon
Arm B: Induction chemotherapy with Thalidomide, Adriamycin and Dexamethasone (TAD) followed by intensive chemotherapy with High-dose Melphalan, followed by maintenance with Thalidomide

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Standard Vincristine, Doxorubicin (Adriamycin®) and Dexamethasone (VAD) induction, thalidomide, Adriamycin®, dexamethasone, melphalan, alpha-interferon

Primary outcome(s)
Event-free survival (i.e. time from registration to induction failure, progression or death, whichever occurs first); the time to failure of patients with induction failure is set at one day. Patients are considered induction failure when they have not achieved at least a Partial response (PR) and are not eligible for further treatment according to protocol.

Key secondary outcome(s))
1. Response (PR and Complete Response [CR])
2. Overall survival measured form the time of registration. Patient still alive or lost to follow up are censored at the date they were last known to be alive
3. Progression free survival (duration of the first response [PR or CR]) measured from the time of achievement of PR (or CR) to date of progression or death from any cause (whichever occurs first)
4. Toxicities of thalidomide and chemotherapy

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Patients with a confirmed diagnosis of multiple myeloma stage II or III according to the Salmon and Durie criteria
2. Age 18 to 65 years inclusive
3. World Health Organisation (WHO) performance status zero to three
4. Negative pregnancy test at inclusion if applicable
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Known intolerance to thalidomide
2. Systemic AL amyloidosis

3. Previous chemotherapy or radiotherapy except two cycles of melphalan/prednisone or local radiotherapy in case of local myeloma progression
4. Severe cardiac dysfunction (New York Heart Association [NYHA] classification II to IV)
5. Significant hepatic dysfunction (serum bilirubin greater than or equal to 30 micromol/l or transaminases greater than or equal to 25 times normal level), unless related to myeloma
6. Patients known to be Human Immunodeficiency Virus (HIV)-positive
7. Patients with active, uncontrolled infections
8. Patients with a history of active malignancy during the past five years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma
9. Patients who are not willing or capable to use adequate contraception during the therapy (all men, all pre-menopausal women)
10. Patients less than or equal to 55 years with a Human Leukocyte Antigen (HLA)-identical sibling who will undergo myeloablative Allogeneic Stem Cell Transplantation (AlloSCT)

Date of first enrolment
27/11/2001

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (Netherlands)

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type

Research organisation

Funder Name
Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (Netherlands)

Funder Name
The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (Netherlands)

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	01/06/2007		Yes	No
Results article	results	11/02/2010		Yes	No
Results article	results	01/12/2015		Yes	No
Protocol article	protocol	01/10/2003		Yes	No