

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/10/2016	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
Dr H M Lokhorst

Contact details
University Medical Centre Utrecht
Department of Haematology
PO Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 250 7230
h.lokhorst@digd.azu.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00028886

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

1. Response (PR and Complete Response [CR])
2. Overall survival measured from 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

Overall study start date

27/11/2001

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

450

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)

Sponsor details

Vrije University Medical Centre (VUMC)
PO Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 2693
hdc@hovon.nl

Sponsor type

Research organisation

Website

<http://www.hovon.nl/>

ROR

<https://ror.org/056kpx27>

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

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