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Randomised phase III study in elderly patients with a multiple myeloma on the value of Thalidomide added to Melphalan plus Prednisone

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 04/02/2011	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR232; Ho49

Study information

Scientific Title

Acronym
HOVON 49 MM

Study objectives
The outcome in arm B is better than in arm A.

Ethics approval required
Old ethics approval format

Ethics approval(s)
METC Ziekenhuis Leyenburg on the 23rd April 2002
Ref: 02.012

Study design
Multicentre randomised open label active controlled parallel trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Patients will be randomized on entry between:
Arm A: 8 cycles of Melphalan + Prednisone
Arm B: 8 cycles of Melphalan + Prednisone + Thalidomide
Non responders will be taken off protocol treatment after 3 cycles of therapy. If after 8 cycles a plateau-phase is reached therapy can be stopped. If after 8 cycles a patient still shows improvement of the disease, therapy will be continued until a plateau phase has been reached. Thalidomide (50 mg/day) in arm B will be continued until disease progression.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Thalidomide, melphalan, prednisone

Primary outcome measure
1. Event free survival (i.e. time from registration to induction failure, death, progression or relapse whichever occurs first)
2. Response rate (complete response [CR] or partial response [PR])

Secondary outcome measures
1. Quality of life
2. Toxicity of the combination therapy
3. Overall survival measured from time of registration. Patients still alive or lost to follow up are censored at the date they were last known to be alive.
4. Progression free survival measured from the time of achievement of PR (or CR) to date of relapse, progression or death from any cause (whichever occurs first)

Overall study start date
01/08/2002

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Patients with a confirmed diagnosis of multiple myeloma stage Ib, II or III according to the Salmon & Durie criteria
2. Age >65 years
3. WHO performance status 0-3
4. Measurable tumorparameter (M-protein or Bence Jones proteïnuria)
5. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
420

Key exclusion criteria
1. Known intolerance to Thalidomide
2. Systemic AL amyloidosis
3. Polyneuropathy
4. Severe cardiac dysfunction (NYHA classification II-IV)
5. Severe pulmonary dysfunction
6. Significant hepatic dysfunction (serum bilirubin ≥30 mmol/l or transaminases ≥25 times normal level), unless related to myeloma
7. Renal failure with dependency on dialysis
8. Patients with active, uncontrolled infections
9. Pre-treatment with cytostatic drug or alpha interferon
10. Patients known to be HIV-positive
11. Patients with a history of active malignancy during the past 5 years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma

Date of first enrolment
01/08/2002

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Haga Hospital, location Leyenburg Hospital,
Den Haag
Netherlands
2504 LN

Sponsor information

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

Sponsor details
Vrije University Medical Centre (VUMC)
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Sponsor type
Research organisation

Website
http://www.hovon.nl/

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type
Charity

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

Funder Name
Dutch Haemato-oncology Association (Stichting Hemato-Oncologie voor Volwassenen Nederland [HOVON]) (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?
Results article	results	01/07/2010		Yes	No
Results article	results	17/03/2011		Yes	No