

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	<input type="checkbox"/> Prospectively registered <input 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 04/02/2011	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

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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 proteinuria)
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

