

Myelo-ablative chemo/radiotherapy and autologous stem cell transplantation as compared to only chemotherapy in patients with multiple myeloma

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 09/11/2007	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.hovon.nl>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Ho24

Study information

Scientific Title

Acronym

HOVON 24 MM

Study objectives

The hypothesis to be tested is that the outcome in arm II (and Allogeneic Bone Marrow Transplant [ABMT]) is better than in arm I.

Objectives:

1. Evaluation of the effect of myeloablative chemo-/radiotherapy and autologous stem cell transplantation in comparison with chemotherapy alone with respect to the mentioned endpoints
2. Assessment of the value of risk factors at diagnosis with dose intensity of treatment

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 controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Multiple Myeloma

Interventions

Patients will be treated with 3 x VAD (vincristine, doxorubicine, dexamethasone). Patients less than or equal to 55 years with a Human Leukocyte Antigen (HLA) identical sibling will proceed to Allo BMT. All other eligible patients will be randomised between:

1. Arm I: PBSC pheresis after cyclophosphamide priming (cyclophosphamide, mesnum, G-CSF), IDM (melphalan, G-CSF) every 8 weeks 2 courses. In case of PR/CR maintenance therapy with IFN-alpha-2a until relapse. PBSCT may be performed after reinduction or relapse
2. Arm II: PBSC pheresis after cyclophosphamide priming (cyclophosphamide, mesnum, G-CSF), IDM (melphalan, G-CSF) q 8 weeks 2 courses. In case of PR/CR intensive treatment with cyclophosphamide/TBI and autologous transplantation, maintenance with IFN-alpha-2a until relapse

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Vincristine, doxorubicine, dexamethasone (VAD), cyclophosphamide, mesnum, Granulocyte Colony Stimulating Factor (G-CSF), melphalan

Primary outcome measure

Remission rate.

Secondary outcome measures

1. Event-free survival
2. Overall survival
3. Quality of life
4. Cost-benefit

Overall study start date

07/11/1995

Completion date

01/04/2000

Eligibility

Key inclusion criteria

At entry:

1. Previously untreated multiple myeloma, stage 2 or 3 according to Salmon and Durie
2. Aged less than 66 years
3. World Health Organization (WHO) performance status 0 - 3
4. Informed consent

For Interferon (IFN) maintenance and Peripheral Blood Stem Cell Transplant (PBSCT) or Allogeneic Bone Marrow Transplant (ABMT):

1. At least Partial Remission (PR) after induction therapy
2. WHO performance status 0 - 2

3. Suitable peripheral stem or bone marrow graft
4. No active infections
5. Absence of severe cardiac, pulmonary, neurologic, psychiatric disease
6. Serum creatinine, bilirubin and transaminases of less than 2.5 x upper limit of normal values
7. Platelet count greater than $50 \times 10^9/l$
8. Absolute neutrophil count greater than $1 \times 10^9/l$
9. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

452

Key exclusion criteria

At entry:

1. Received more than 2 courses of melphalan, prednisone or vincristine, melphalan (M), cyclophosphamide, prednisone (VMCP)
2. Severe cardiac disease (= severe heart failure requiring symptomatic treatment or a cardiac ejection fraction of less than 45% with presence of normal hemoglobin), severe pulmonary, neurologic or metabolic disease- Inadequate liver function, i.e., bilirubin greater than or equal to 25 x upper normal value
3. Prior malignancies except non-melanoma skin tumors or stage 0 (in situ) cervical carcinoma
4. Prior extensive radiotherapy involving the myelum (precluding total body irradiation)

Date of first enrolment

07/11/1995

Date of final enrolment

01/04/2000

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center 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)
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Sponsor type

Research organisation

Website

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

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Roche Nederland B.V. (The Netherlands)

Funder Name

Amgen (The Netherlands)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Johnson & Johnson (The Netherlands)

Alternative Name(s)

Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Commission for Medical Applied Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (The Netherlands)

Funder Name

Novartis Pharma B.V. (The Netherlands)

Funder Name

Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON) (The 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?
Other publications		15/03/2003		Yes	No
Results article		01/05/2003		Yes	No
Other publications		01/05/2004		Yes	No