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

Submission date
20/12/2005

Registration date
20/12/2005

Last Edited
09/11/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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 x 10^9/l
8. Absolute neutrophil count greater than 1 x 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/056kpdx27

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