ISRCTN01207094 https://doi.org/10.1186/ISRCTN01207094

Autologous stem cell transplantation for patients with amyloid light chain (AL) amyloidosis

Submission date	Recruitment status
26/10/2010	No longer recruiting
Registration date	**Overall study status**
11/11/2010	Completed
Last Edited	**Condition category**
13/02/2015	Nutritional, Metabolic, Endocrine

[_] 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

Contact name
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3508 GA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ho41

Study information

Scientific Title
Autologous stem cell transplantation for patients with AL amyloidosis. A prospective phase II study

Acronym
HOVON 41 AL AMYLOIDOSIS

Study objectives
Treatment with myelo-ablative chemotherapy and autologous stem cell transplantation in patients with AL amyloidosis is feasible and efficacy meets the expectations as described in the protocol.

Further reading:
New Eng.J.Med. 2008 Jan3; 358(1):92: author reply 92-3.
High-dose melphalan versus melphalan plus dexamethasone for AL amyloidosis.
Lokhorst HM, Hazenberg BP, Croockewit A.
http://www.ncbi.nlm.nih.gov/pubmed/18172953

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of University Medical Centre (UMC) Utrecht approved on the 1st of August 2000

Study design
Prospective multicentre single arm non-randomised trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Amyloid light-chain (AL) amyloidosis

Interventions
Patients will be undergo the following treatments:
1. VAD induction treatment (3-4 weeks) courses, consisting of vincristine, doxorubicin (Adriamycin®), dexamethasone
2. Stem cell mobilization with G-CSF
3. Melphalan 200 mg/m2 treatment, followed by peripheral blood stem cell transplantation or unprocessed G-CSF-primed whole blood reinfusion

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
VAD (Vincristine, doxorubicin [Adriamycin®], dexamethasone)

Primary outcome measure
1. Response (clonal and clinical)
2. Overall survival.

Secondary outcome measures
Percentage of patients that will ultimately receive an autologous transplant.

Overall study start date
04/09/2000

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Age 18-65 years incl.
2. Monoclonal Gammopathy of Undetermined Significance (MGUS), multiple myeloma stage I
3. Histologically documented systemic AL amyloidosis
4. Untreated or previously treated with maximal 3 courses of melphalan and prednisone
5. The patient must give informed consent according to the rules of the hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Prior malignancies diagnosed less than 5 years ago, except non-melanoma skin tumours or stage 0 (in situ) cervical carcinoma
2. Patients with familial variants of systemic amyloidosis
3. Severe pulmonary, neurologic, psychiatric, cardiac, liver or metabolic disease not related to AL amyloidosis

Date of first enrolment
04/09/2000

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Dept. of Hematology
Utrecht
Netherlands
3508 GA

Sponsor information

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

Sponsor details
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
P.O. box 5201

Rotterdam
Netherlands
3008 AE

Sponsor type
Research organisation

Website
http:\\www.hovon.nl

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type
Research organisation

Funder Name
Dutch-Belgian Cooperative Trial Group for Hematology Oncology (HOVON) (Netherlands)

Funder Name
Dutch Cancer Fund (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?
Results article	results	01/05/2015		Yes	No