

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

Submission date 26/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/11/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/02/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Henk Lokhorst

Contact details
Dept. of Hematology
UMCU
P.O. box 85500
Utrecht
Netherlands
3508 GA

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

1. Response (clonal and clinical)
2. Overall survival.

Key secondary outcome(s)

Percentage of patients that will ultimately receive an autologous transplant.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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)

ROR

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

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes