HD 16 for early stages, treatment optimization trial in the first-line treatment of early stage Hodkgin lymphoma; treatment stratification by means of FDG-PET.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lymphomas Hodgkin's disease
Study type	Interventional

Summary

ID

NL-OMON47064

Source
ToetsingOnline

Brief title
HD 16 for early stages.

Condition

- Lymphomas Hodgkin's disease
- Lymphomas Hodgkin's disease

Synonym
malignant lymphoma; Hodgkin's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Early stages, Hodgkin lymphoma

Outcome measures

Primary outcome

Progression Free Survival (PFS)

Secondary outcome

CR rate

Overall survival

late toxicity of treatment

Secondary maligancy rate

Rate of patients who are PET positive and PET negative after to 2 cycles of

ABVD

Study description

Background summary

The German Hodgkin Study Group Center (GHSG) in Cologne is responsible for developing trials to improve the treatment of Hodgkin lymphoma. Improvements in radiotherapy and the introduction of polychemotherapy have contributed to the development of an incurable malignant disease into an oncological disease in adults that actually has the best prognosis of all. Relevant improvements in diagnostics and treatment are based on a stringent implementation of quality standards in the areas of pathology, radiology, nuclear medicine, radiotherapy
and chemotherapy.

Due to its superior tumor control and low toxicity level, ABVD is the GHSG*s

standard regimen for early stage HL patients. The question whether 2 x ABVD is equivalent to 2 x AVD cannot be answered until the final analysis of the HD13 trial has been drawn up. Due to the results of the HD10 trial, 20Gy IF-RT is the new standard within the scope of clinical trials. If the final analysis of HD13 reveals that 2 x ABVD is equivalent to 2 x AVD, also this new standard would possibly be implemented into this trial.

Study objective

The aim of the trial is to individualize treatment for each patient by adapting it to early response and to treat only those patients with addiotional radiotherapy who show an inadequate treatment response.
The degree of treatment response is determined by means of FDG-PET after 2 cycles of ABVD.
The aim for patients who show a good response is to reduce the toxicity of therapy without impairing treatment results.

With this trial it is to be confirmed that the experimental arm (2x ABVD with or without radiotherapy) is non-inferior to standard treatment (2x ABVD plus 20 Gy radiotherapy) with respect to the primary endpoint of PFS.

Study design

Prospective, randomized multicenter study with treatment stratification by means of FDGPET-scan performed after 2 courses of chemotherapy.

In the HD16 trial, early response after 2 cycles of chemotherapy is examined by means of FDG-PET. Patients who are randomized into the standard arm receive IF-RT (20 Gy), independent of their PET-2 result. Patients who are randomized into the experimental arm receive IF-RT (20 Gy) in case of a positive PET result (PET-2 positive). Patients with a negative PET (PET-2 negative) don't receive any further treatment.

The randomization result will not be disclosed until the results of the restaging examinations and the FDG-PET assessment by the central PET panel have been established.

Intervention

For PET-2 negative patients: end of treatment

For PET-2 positive patients: 20 Gy Involved Field Radiotherapy

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Histologically proven primary diagnosis of Hodgkin lymphoma;
2. Stage: I and II without risk factor
3. Patient had no previous treatment for HL;
4. Age at entry: 18 - 75 years;
5. 6. Normal organ function (except HL-related);
6. Negative HIV test
7. In women: negative pregnancy test
8. Life expectancy > 3 months

Exclusion criteria

1. Incomplete diagnosis of the disease stage;
2. Prior or concurrent disease that prevents treatment according to protocol;
3. HL as composite lymphoma;
4. Prior chemotherapy or radiation;
5. Malignant disease within the last 5 years (exceptions: basalioma, carcinoma in situ of the cervix uteri, completely resected melanoma TNMpT1);
6. Pregnancy, lactation;
7. WHO activity index > 2;
8. Long-term administration of corticosteroids (e.g. for chronic polyarthritis) or antineoplastic drugs (e.g. methotrexate)
9. Non-compliance

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-03-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bleomycin
Generic name:	Bleomycin
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Doxorubicine
Generic name:	Doxorubicin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	DTIC
Generic name:	Dacarbazine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Vinblastine
Generic name:	Vinblastine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-01-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR200700447424-NL
ClinicalTrials.gov	NCT00736320
CCMO	NL32169.029.10

Study results

Date completed: 29-12-2020

Actual enrolment: 19

Summary results
Trial is onging in other countries