HD17 for Intermediate Stage Hodgkin Lymphoma - Treatment Optimization Trial in the First-Line Treatment of intermediate Stage Hodgkin lymhoma; Therapy stratification by means of FDG-PET

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

Summary

ID

NL-OMON47350

Source
ToetsingOnline

Brief title
HD 17 for intermediate 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: Hodgkin Lymphoma, Intermediate stage

Outcome measures

Primary outcome

Progression-free survival (PFS)

Secondary outcome

- CR rate

- Overall survival (OS)

- Proportion of patients with good / inadequate response to 2 cycles of

escalated BEACOPP and 2 cycles of ABVD

- Late toxicities of treatment

- Secondary malignancies

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.

The current treatment standard for patients with intermediate stage Hodgkin lymphoma is a combined chemo- and radiotherapy. This kind of treatment provides excellent cure rates, but is associated with treatment-related late toxicities. According to present knowledge, these are mainly due to the combined use of both treatment modalities, so if radiotherapy could be dispensed with, this would be a significant therapeutic advancement. By using FDG-PET after 4 cycles of chemotherapy it might be possible to identify those patients in whom radiotherapy can be omitted.

Also in this trial 30 Gy involved-field radiotherapy, which is well-established, is compared to involved-node radiotherapy, which marks an interesting advancement in terms of the target volume definition. It is expected that acute and late toxicities can be further minimized with this treatment approach while efficacy will be maintained.
Besides, the trial will show whether radiotherapy can be dispensed within patients who are PET negative after chemotherapy.

Study objective

The aim of this trial is to individualize and thus to optimize treatment for each patient by adapting it to the individual response.
The treatment response is determined by means of FDG-PET after 2 cycles of escalated BEACOPP + 2 cycles of ABVD.
The aim for patients who show a good response is to reduce the toxicity of therapy without impairing treatment results. Consequently, in future only those patients who show an inadequate response to chemotherapy would receive additional radiotherapy.

IN radiotherapy is introduced to investigate whether this new target volume definition leads to a reduction in toxicity while maintaining the PFS rate.

Study design

Prospective, randomized multicenter study with treatment stratification by means of FDGPET-scan performed after 4 courses of chemotherapy.

STANDARD ARM:
2 x escalated BEACOPP + 2 x ABVD + 30 Gy IF-RT, independent of the FDG-PET result

EXPERIMENTAL ARM:
2 x escalated BEACOPP + 2 x ABVD for all patients, then stratification by means of FDG-PET;
for PET positive patients: + 30 Gy IN-RT
for PET negative patients: no RT

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-negative patients after 4 courses of chemotherapy: end of treatment
For PET-positive patients after 4 courses of chemotherapy: 30 Gy Involved Node Radiotherapy

Study burden and risks

Those patients in whom radiotherapy is omitted have a higher risk of relapse. However, from the GHSG*s point of view this is a manageable risk because of the availability of effective treatments that lead to permanent cure in a major part of relapsed patients.
Besides, the trial will be monitored regularly regarding imbalances between the treatment arms in terms of the number of relapsed patients or patients with primarily progressive disease, and it would be terminated early in case of a significantly increased number of events.
In summary, from the GHSG*s perspective the potential benefit that may be gained from the HD17 trial clearly outweighs the risks described above.

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

* Histologically proven Hodgkin lymphoma
* Newly diagnosed, no previous treatment
* Stage I, IIA with RF a-d; stage IIB with RF c, d
(a: large mediastinal mass, b: extranodal disease, c: high ESR, d: * 3 lymph node areas)
* Age: 18-60 years
* Patient had no previous treatment for HL
* Normal organ function (except HL-related);
* Life expectancy > 3 months.

Exclusion criteria

* Composite lymphoma
* Previous malignancy, prior chemotherapy or radiotherapy
* Concurrent diseases which preclude protocol treatment
* Pregnancy, lactation
* Non-compliance
* WHO activity index > 2
* Antiepileptic treatment
* Concurrent diseases which preclude protocol treatment
* Long-term administration of corticosteroids (e.g. for chronic polyarthritis) or antineoplastic drugs (e.g. azathioprine, methotrexate)

Study design

Design

Study phase: 3

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2013
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:	Etoposide
Generic name:	Etoposide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Vinblastine
Generic name:	Vinblastine

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2018
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	EUCTR2007-005920-34-NL
ClinicalTrials.gov	NCT01356680
CCMO	NL41262.029.12

Study results

Results posted: 20-04-2021

First publication
24-03-2021