EuroNet-Paediatric Hodgkin*s Lymphoma Group ;Second International Inter-Group Study for Classical Hodgkin*s Lymphoma in Children and Adolescents

Published: 25-04-2016
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The aim of this study is to reduce the indication for RT without compromising cure rates. To investigate if intensified consolidation therapy (DECOPDAC-21) compared to standard consolidation therapy (COPDAC-28) can compensate for reduction in RT.

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

Summary

ID

NL-OMON53041

Source
ToetsingOnline

Brief title
EuroNet-PHL-C2

Condition

- Lymphomas Hodgkin's disease

Synonym
Classical Hodgkin□s Lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Justus-Liebig-University Giessen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adolescents, Children, Classical type, Hodgkin's Lymphoma

Outcome measures

Primary outcome

- To increase event-free survival (EFS) in ERA PET-negative TL-2 and TL-3 patients without radiotherapy by using intensified consolidation chemotherapy (DECOPDAC-21).

- To demonstrate in ERA PET-positive TL-2 and TL-3 patients that the combination of intensified consolidation chemotherapy (DECOPDAC-21) plus restricted field radiotherapy based on the LRA is comparable to the standard consolidation chemotherapy (COPDAC-28) plus standard involved node radiotherapy.

Secondary outcome

- Evaluation of haematotoxicity during different chemotherapy regimens.

- For ERA positive patients to compare the late response assessment positivity rates after consolidation chemotherapy with COPDAC-28 or DECOPDAC-21.

Outcome measures

The primary outcome is event-free survival (EFS) defined as time from start of treatment until the first of the following events:

• progression/relapse of disease

• secondary malignancy

• death from any cause.

Secondary outcomes include efficacy, quality and safety endpoints.

Study description

Background summary

The standard treatment of classical Hodgkin lymphoma is chemotherapy in combination with radiotherapy. Although the overall prognosis with this treatment is excellent, both short and long term complications are of great concern. The standard treatment of this protocol (EuroNet-PHL-C2) is based on the EuroNet-PHL-C1 protocol. The results of the EuroNet-PHL-C1 protocol showed an event free survival (EFS) of > 85% and the substitution of procarbazine by dacarbazine appeared equally effective with less gonadotoxic effects. Moreover, radiotherapy (RT) could be omitted in half of the patient population.

Study objective

The aim of this study is to reduce the indication for RT without compromising cure rates. To investigate if intensified consolidation therapy (DECOPDAC-21) compared to standard consolidation therapy (COPDAC-28) can compensate for reduction in RT.

Study design

EuroNet-PHL-C2 is risk-stratified (defining chemotherapy) and response adapted (defining radiotherapy). Former treatment groups (TG) of the EuroNet-PHL-C1 trial are reassigned into treatment levels (TL). Early stage patients (former TG-1) with one of the new risk factors (ESR > 30 mm and tumor volume > 200 ml) will be reassigned into TL-2.

All TL-2 and TL-3 patients will be randomized between respectively 2 or 4 standard COPDAC-28 or intensified DECOPDAC-21 consolidation chemotherapy cycles.

Response to treatment is based on FDG-PET scans after the first two cycles of OEPA (early response assessment; ERA). RT indication will be restricted. For all patients with an adequate response at ERA, RT will be omitted. Patients in TL-1 with an adequate response will receive 1 cycle of COPDAC-28.

For patients in TL-2 and TL-3 with an inadequate response at ERA, a late response assessment (LRA) will be introduced after respectively 2 or 4 cycles of consolidation chemotherapy. Patients receiving standard consolidation therapy (COPDAC-28) will receive a boost of RT on LRA FDG-PET positive spots besides the on ERA based standard RT. Patients randomized for intensified consolidation chemotherapy (DECOPDAC-21) will receive no RT or restricted field RT based on the LRA.

For Hodgkin Lymphoma, FDG-PET scans are formally integrated in the protocol. Patient material and data will be collected centrally.

Intervention

Not applicable

Study burden and risks

There is no increased risk or burden compared for the standard treatment consisting of chemo- and radiotherapy. It is possible that the intensified chemotherapy has more side-effects or toxicity compared to the standard therapy.

Contacts

Public
Justus-Liebig-University Giessen

Feulgenstraße 12
Giessen 35385
NL
Scientific
Justus-Liebig-University Giessen

Feulgenstraße 12
Giessen 35385
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

• histologically confirmed primary diagnosis of classical Hodgkin*s lymphoma
• patients under 18 years of age on the date of written informed consent. In specialized Teenage and Young Adult (TYA) units in France, Italy and UK patients up to under 25 years of age can also be enrolled. Lower age limits will be country specific according to national laws or formal insurance requirements that may preclude very young patients.
• written informed consent of the patient and/or the patient*s parents or guardian according to national laws
• negative pregnancy test within 2 weeks prior to starting treatment for female patients with childbearing potential

Exclusion criteria

• prior chemotherapy or radiotherapy for other malignancies
• pre-treatment of Hodgkin*s lymphoma (except for 7-10 days steroid pre-phase of a large mediastinal tumour)
• diagnosis of lymphocyte-predominant Hodgkin*s lymphoma
• other (simultaneous) malignancies
• contraindication or known hypersensitivity to study drugs
• severe concomitant diseases (e.g. immune deficiency syndrome)
• known HIV-positivity
• residence outside the participating countries where long term follow-up cannot be guaranteed
• pregnancy and/or lactation
• patients who are sexually active and are unwilling to use adequate contraception during therapy and for one month after last trial treatment
• current or recent (within 30 days prior to date of written informed consent) treatment with another investigational drug or participation in another interventional clinical trial

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:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-10-2016
Enrollment:	124
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Adriamycin
Generic name:	Doxorubicin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cyclophosphamide
Generic name:	Cyclophosphamide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Dacarbazine
Generic name:	Dacarbazine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Etoposide

Generic name:	Etoposide / Etopophos
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Vincristine
Generic name:	Vincristine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	25-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-09-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-05-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-01-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	16-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-09-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-10-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2012-004053-88-NL
CCMO	NL47032.078.16