First international Inter-Group Study for classical Hodgkin's Lymphoma in Children and Adolescents

Published: 23-11-2010
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The objective of the study is to diminish the amount of chemotherapy and/ or radiotherapy for children with Hodgkin lymphoma who are likely to receive too much treatment with current treatment protocols.

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

Summary

ID

NL-OMON41689

Source
ToetsingOnline

Brief title
EuroNet-PHL-C1

Condition

- Lymphomas Hodgkin's disease

Synonym
classical Hodgkin's Lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

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

Outcome measures

Primary outcome

1. Are 5 year event free survival (EFS) rate estimates in patients with adequate response after 2 OEPA treated without radiotherapy consistent with a target EFS rate of 90% in all treatment groups? 2. Can Procarbazine be safely replaced by Dacarbazine in therapy groups TG-2 and TG-3 without a deterioration of EFS (randomised comparison of COPDAC and COPP)? 3. Description of treatment outcome to a standardised risk adapted relapse strategy

Secondary outcome

1. Is the 5 year event free survival (EFS) rate in patients with inadequate response after 2 OEPA who receive standard involved field radiotherapy consistent with a target EFS rate of 90% estimates in all treatment groups? 2. Does substitution of Dacarbazine for Procarbazine in TG-2 and - 3 patients decrease the rate of infertility in males and premature ovarian failure for females? 3. Does a positive PET finding before planned high-dose chemotherapy with autologous stem cell transplantation have a negative prognostic significance?

Study description

Background summary

Current treatment protocols in paediatric Hodgkin*s lymphoma consist of chemotherapy combined with or without radiotherapy. With these treatment

modalities survival rates are high (> 90%). The remaining challenges for further treatment optimisation are: reduction of acute and long-term toxicity of the chemotherapy and radiotherapy employed and reduction of the amount of treatment in those children who are currently over-treated. The standard arm in this protocol is based on the German (GPOH-HD) studies applied for Hodgkin lymphoma in children the last decades.

Study objective

The objective of the study is to diminish the amount of chemotherapy and/ or radiotherapy for children with Hodgkin lymphoma who are likely to receive too much treatment with current treatment protocols.

Study design

Based on the disease stage patients will be stratified in three different treatment groups. The disease stage determines the chemotherapy dosage for each patient. All patients start with two cycles of OEPA. Thereafter, response assessment will be done with a FDG-PET scan. Radiotherapy after completion of chemotherapy will be omitted in patients with adequate response. For Hodgkin*s lymphoma a FDG-PET currently is routinely used in most centres. Results of FDG-PET are now formally integrated both into staging and response assessment.
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Intervention

In treatment group two and three patients are randomized for the standard course COPP (with Procarbazine) and the intervention course COPDAC (with Dacarbazine). Procarbazine can cause infertility. Substitution of Dacarbazine for Procarbazine should decrease the rate of infertility in males and premature ovarian failure in females, with the same efficacy.

Study burden and risks

Hodgkin lymphoma can only be cured by radiotherapy and/ or chemotherapy. Toxicity caused by these treatment modalities is known. There is no extra risk for patients treated according to the intervention arm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* diagnosis of classic Hodgkin*s lymphoma
* patient aged under 18 years at time of diagnosis
* written informed consent of the patient and/or the patient*s parents or guardian according to national laws

Exclusion criteria

* pre-treatment of Hodgkin*s lymphoma differing from study protocol (except recommended pre-phase therapy of a large mediastinal tumour)
* known hypersensitivity or contraindication to study drugs
* diagnosis of lymphocyte predominant Hodgkin*s lymphoma
* prior chemotherapy or radiotherapy
* other (simultaneous) malignancies
* pregnancy and / or lactation
* females who are sexually active refusing to use effective contraception (oral contraception, intrauterine devices, barrier method of contraception in conjunction with spermicidal jelly or surgical sterile)

* Current or recent (within 30 days prior to start of trial treatment) treatment with another investigational drug or participation in another investigational trial
* severe concomitant diseases (e.g. immune deficiency syndrome)
* known HIV positivity

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):	05-07-2011
Enrollment:	65
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Déticène
Generic name:	Dacarbazine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Eposin
Generic name:	Etoposide
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Natulan
Generic name:	Procarbazine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-11-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-09-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	22-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-06-2015
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	EUCTR2006-000995-33-NL
CCMO	NL33537.078.10

Study results

Date completed:	30-10-2018
Results posted:	25-11-2019
Actual enrolment:	34

First publication
17-11-2019