

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

Published: 23-11-2010

Last updated: 04-05-2024

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.

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

Public

Stichting Kinderoncologie Nederland

Postbus 43515

Den Haag 2504 AM
NL
Scientific
Stichting Kinderoncologie Nederland

Postbus 43515
Den Haag 2504 AM
NL

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