Hodgkin-biomarkers

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28180

Bron
Nationaal Trial Register

Verkorte titel
Hodgkin-biomarkers

Aandoening

Pediatric Hodgkin lymphoma

Ondersteuning

Primaire sponsor: Erasmus MC - Sophia
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The aim of this project is to identify biomarkers and novel therapeutic targets for pediatric Hodgkin lymphoma.

Toelichting onderzoek

Achtergrond van het onderzoek

With this project we hope to identify biomarkers and novel therapeutic targets for pediatric Hodgkin lymphoma.

2.1 Population (base)
All patients with a suspected diagnosis of Hodgkin lymphoma will be offered to participate in this study. Patients that have a confirmed diagnosis of classical Hodgkin Lymphoma will be checked on the inclusion and exclusion for the Hodgkin lymphoma group (paragraph 2.2) . Patients that do not have the diagnosis classical Hodgkin Lymphoma will be checked on the inclusion and exclusion criteria for the control group (paragraph 2.3). If a patient isn't eligible for both groups this will be considered as a screen failure and remaining bodily material will be destroyed

Doel van het onderzoek

Although classical Hodgkin Lymphoma (CHL) in pediatric patients has a good prognosis, the outcome is associated with a substantial proportion of treatment-related toxicity and still about 10-20% of the patients progress during or relapse after treatment. Strikingly, therapeutic regimens have not changed much during the past decades. Current treatment protocols rely on chemo- and radiotherapy, whereby patients are classified at diagnosis into three different treatment groups based on a clinical staging system. Radiotherapy can be omitted based on Fluoro-Deoxyglucose-Positron emission tomography CT (PET-CT) treatment response.

HL is considered an immunological disease, where reactive cells in the tumor microenvironment greatly outnumber malignant Hodgkin- and Reed-Sternberg (HRS) cells. The microenvironment supports proliferation and survival of HRS cells. Due to active crosstalk between HRS cells and their microenvironment, serum biomarkers should be detectable and may be a surrogate for lymphoma viability. HL biology impedes development of in vitro and in vivo assays for functional studies to discover new therapeutics. Genetic analysis of malignant Hodgkin cells has been hampered by their scarcity and has largely been done with laser-dissected samples. In addition, apart from a clinical staging system at diagnosis, there have been no prognostic molecular markers to stratify patients into different therapy groups. Taken together this calls for efforts to identify biomarkers and get an in-depth understanding of HL immunology and biology to discover new therapeutic targets en less toxic therapies.

Onderzoeksopzet

Baseline characteristics

Clinical parameters including age, sex, stages according to the Cotswolds revision of the Ann

Arbor staging system, histology and the presence of B symptoms will be collected. The following laboratory parameters will be recorded at time of diagnosis and during follow-up at the same time points as serum and blood samples for biomarker identification are taken: Erythrocyte sedimentation rate (ESR), leukocyte count and differentiation, lymphocyte subpopulations, thrombocyte count, hemoglobin, creatinine, albumin and C-reactive protein. EBV status and treatment regime will be registered at diagnosis.

Blood biomarkers

Serial serum and blood samples will be collected at diagnosis (baseline) and at fixed time points during treatment and follow-up

Onderzoeksproduct en/of interventie

Not applicable,

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Hodgkin lymphoma group

In order to be eligible to participate in the Hodgkin lymphoma group, a subject must meet all of the following criteria:
- Diagnosis of classical Hodgkin Lymphoma confirmed by reference pathology
- Patient aged below 18 at time of diagnosis
- Treatment according the European Network of Paediatric Hodgkin`s Lymphoma Second International Inter-Group Study for Classical Hodgkin's Lymphoma in Children and Adolescents (EuroNet-PHL-C2) protocol or treatment for relapsed or refractory patients.
- Written informed consent of the patient and/or the patient's parents or guardians according to national laws

Control Group
In order to be eligible to participate in the control group a subject must meet all of the following criteria:
- No diagnosis of classical Hodgkin Lymphoma confirmed by reference pathology
- Patient aged below 18 at time of diagnosis
- Written informed consent of the patient and/or the patient's parents or guardians according to national laws

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- HIV positivity
- Other underlying immunologic disorders, with the exception of Epstein Barr Virus

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-11-2016

Aantal proefpersonen:	320
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54726
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6706
NTR-old	NTR6876
CCMO	NL52872.078.15
OMON	NL-OMON54726

Resultaten