Inter-groep studie voor de behandeling van kinderen en adolescenten met een B-cel non-Hodgkin lymfoom of B-ALL: Beoordeling van de werkzaamheid en veiligheid van rituximab bij patiënten met een hoog risico.

Gepubliceerd: 14-03-2012 Laatst bijgewerkt: 13-12-2022

Rituximab (antiCD20) in association with chemotherapy has extended the survival of adult patients with diffuse large B-cell lymphoma (DLBCL). Also in adults, there is accumulating evidence of a benefit of Rituximab for Primary mediastinal large B-...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21840

Bron
NTR

Verkorte titel
Inter-B-NHL ritux 2010

Aandoening

childhood B-cell lymphoma
childhood PMLBL

B-cel non-Hodgkin lymfoom (B-NHL) bij kinderen
B-cel acute lymfatische leukemie (B-ALL) bij kinderen

Ondersteuning

Primaire sponsor: Institut Gustave Roussy
114, rue Edouard Vaillant
94 805 - Villejuif
France
Overige ondersteuning: Institut Gustave Roussy
Roche

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Event Free Survival.

Toelichting onderzoek

Achtergrond van het onderzoek

Phase III - non PMLBL patients:

Prephase (COP) for all groups followed by:

1. Group B: 4 courses: 2 COPADM + 2 CYM, with MTX 3g/m²;

2. Group C: 6 courses: 2 COPADM + 2 CYVE + 2 maintenance courses, with MTX 8g/m², in 4h in C1, in 24h in C3 (except the 1st course).

Phase II – PMLBL patients:

6 courses of DA-EPOCH-R.

Participating countries:

Italy, Belgium, UK, Netherlands, Hungary, Poland, Spain, France, North America and Oceani. (COG will coordinate centers localized in USA, Canada, Australia, New Zealand)

Doel van het onderzoek

Rituximab (antiCD20) in association with chemotherapy has extended the survival of adult patients with diffuse large B-cell lymphoma (DLBCL). Also in adults, there is accumulating evidence of a benefit of Rituximab for Primary mediastinal large B-cell lymphoma (PMLBL) patients.

This large randomized trial is necessary to evaluate whether rituximab can add benefit to the current chemotherapy regimen for childhood B-cell lymphoma and PMLBL.

Onderzoeksopzet

Toxicity will be measured during the study after each course. Interim analyses for efficacy and futility will be performed approximately after 1/3 of EFS events and yearly thereafter.

Onderzoeksproduct en/of interventie

Patients will be randomized to standard treatment or standard treatment with Rituximab. Patients in the intervention group will receive 6 injections of rituximab to a standard LMB chemotherapy regimen. The control group will receive LMB chemotherapy alone.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children and adolescents aged until 18 years with untreated advanced stage B-cell NHL or B-AL.

HISTOLOGY AND STAGING DISEASE:

Phase III study:

1. Histologically or cytologically proven B-cell malignancies, either Burkitt lymphoma or B-AL (=Burkitt leukaemia = L3-AL) or diffuse large B-cell NHL or aggressive mature B-cell NHL non other specified or specifiable;

2. Stage III with elevated LDH level (“B-high”), [LDH > twice the institutional upper limit of the adult normal values (> Nx2)] or any stage IV or B-AL.

Phase II study:

1. Histolo-cytologically proven PMLBL;

2. PMLBL without CNS involvement.

GENERAL CONDITIONS:

1. 6 months to less than 18 years of age at the time of consent;

2. Males and females of reproductive potential must agree to use an effective contraceptive method during the treatment, and after the end of treatment: during twelve months for women, taking into account the characteristics of rituximab and during five months for men, taking into account the characteristics of methotrexate.

INITIAL WORK-UP:

Complete initial work-up within 8 days prior to treatment.

OTHERS:

1. Able to comply with scheduled follow-up and with management of toxicity;

2. Signed informed consent from patients and/or their parents or legal guardians.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

HISTOLOGY AND STAGING DISEASE:

1. Follicular lymphoma, MALT and nodular marginal zone are not included into this therapeutic study;

2. In phase II study (PMLBL) patients with CNS involvement are not eligible.

GENERAL CONDITIONS:

1. Patients with congenital immunodeficiency, chromosomal breakage syndrome, prior organ transplantation, previous malignancy of any type, or known positive HIV serology;

2. Evidence of pregnancy or lactation period;

3. There will be no exclusion criteria based on organ function.

PRIOR THERAPY:

Past or current anti-cancer treatment except corticosteroids during less than one week.

EXCLUSION CRITERIA RELATED TO RITUXIMAB:

1. Tumor cell negative for CD20 (absence of result due to technical problems in the presence of other characteristics suggestive of BL/DLBCL, including genetic and phenotypic features, is not an exclusion criteria);

2. Prior exposure to rituximab;

3. Severe active viral infection, especially hepatitis B. Severe infection (such as sepsis, pneumonia, etc..) should be clinically controlled at the time of randomisation. Contact the

national co-investigator for further advice if necessary;

4. Hepatitis B carrier status history of HBV or positive serology.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	19-12-2011
Aantal proefpersonen:	640
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3207
NTR-old	NTR3358
Ander register	EudraCT / CCMO : 2010-019224-31 / NL37584.018.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A