A trial to investigate the efficacy and feasibility of treatment with dose adjusted EPOCH-R (DA-EPOCH-R), adapted to risk profile in patients with newly diagnosed Burkitt lymphoma.

Gepubliceerd: 14-12-2012 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26111

Bron
Nationaal Trial Register

Verkorte titel
DA-EPOCH-R trial

Aandoening

Burkitt lymphoma, Burkitt Lymfoom

Ondersteuning

Primaire sponsor: VU University Medical Center Amsterdam
Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. 2 years overall survival (OS; time from registration. Patients still alive or lost to follow up are censored at the date they were last known to be alive) and progression free survival (PFS; i.e. time from registration to progression or death from any cause, whichever comes first);
2. Number of cycles of the DA-EPOCH-R scheme completed on an out-patient –clinic basis.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: Phase II.

Patient population:

Patients with newly diagnosed Burkitt lymphoma ≥ 18years.

Study objective:

To asses efficacy (PFS and OS at 2 years) and feasibility (defined as number of cyles administered on an out-patient-clinic basis) of risk-adapted DA-EPOCH-R in patients with newly diagnosed Burkitt lymphoma

Study design:

A prospective, monocenter, open label, non-randomized clinical trial:

1. Low risk patients will receive 3 cycles of DA-EPOCH-RR;

2. High risk patients will receive 6 cycles of DA-EPOCH-R;

3. CSF cytology will be done in all patients;

4. High Risk patients with CSF negative will receive prophylactic intrathecal treatment;

5. Low risk patients with CSF negative (1 normal LP and no clinical suspicion) will not receive prophylactic intrathecal treatment;

6. All patients with CSF positive will receive active intrathecal treatment;

7. FDG-PET/CT pre- and post-cycle 2 in all patients. Low risk patients with positive low-dose PET/CT (positive defined as a score ≥ 3 according to Deauville criteria (appendix B1) after 2 cycles will receive 6 cycles of DA-EPOCH-R;

8. A total of 22 patients will be enrolled in the protocol.

Doel van het onderzoek

The DA-EPOCH-R regimen represents a major paradigm shift for the treatment of BL. Whereas standard treatment relies on dose density and intensity based on methotrexate and cytarabin to achieve adequate cell kill, DA-EPOCH-R relies on a pharmacodynamic based infusional schedule to improve the therapeutic index of chemotherapy. Based on the pilot results presented by Dunleavy at ICML 2011, DA-EPOCH- R appears to provide a high rate of cure with significantly lower treatment toxicity and tumor lysis syndrome compared to standard treatment. As such, DA-EPOCH-R may provide a major treatment advance in BL by lowering morbidity, mortality, and cost, while maintaining or possibly improving efficacy. The current protocol is aims to confirm the results obtained with DA-EPOCH-R in BL in Dutch general hematology practice, as this protocol has been conducted primarily by the NIH.

Onderzoeksopzet

Total expected study duration is 5 years.

Study start (FPFV): Nov 2012;

Recruitment end (LPFV): Nov 2015;

Study end (LPLV): Nov 2017;

Completion of Clinical Study Report (CSR): June 2018;

Publication date: June 2018.

Onderzoeksproduct en/of interventie

1. Low risk patients (3 cycles of Dose Adjusted EPOCH with 2xRituximab);

2. High risk patients (6 cycles of DA-EPOCH-Rituximab).

EPOCH is Etoposide, Prednisone, Vincristine, Cyclophosphamide, Doxorubicin.

Low risk patients with a positive PET-CTscan after 2 cycles of DA-EPOCH-RR will receive 4 cycles of DA-EPOCH-R.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. First diagnosis of Burkitt lymphoma, histological confirmed according to the WHO classification 2008;

2. Age ≥ 18 years;

3. No prior treatment except local radiation or short course steroids ≤ 1 mg/kg for acute symptoms;

4. All disease stages;

5. HIV negative or positive;

6. ECOG-WHO status 0-3, status 4 only if disease related;

7. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. All histopathological diagnoses other than BL according to the WHO classification 2008, irrespective of the presence of MYC rearrangement;

2. Inadequate renal function or creatinine clearance < 50 ml/min unless lymphoma related;

3. Inadequate hepatic function: bilirubin > 2 * ULN (total) except patients with Gilbert's syndrome as defined by > 80% unconjugated;

4. Inadequate hematological function ANC < 1x109/l and platelets < 75x109 /l unless lymphoma related;

5. leukemic Burkitt lymphoma, defined as >30% blasts in bone-marrow and/or peripheral blood, without significant lympadenopathy;

6. Female subject of child-bearing potential not willing to use an acceptable method of birth control (i.e., a hormonal contraceptive, intra-uterine device, diaphragm with spermicide, condom with spermicide, or abstinence) for the duration of the study and one year beyond treatment completion;

7. Female subject pregnant or breast-feeding;

8. Male subject unwilling to use an acceptable method for contraception for the duration of the study and one year beyond treatment completion;

9. History of a prior invasive malignancy in past 5 years;

10. Active symptomatic ischemic heart disease, myocardial infarction, or congestive heart failure within the past year. If echo is obtained the LVEF should exceed 40%;

11. Serious concomitant medical illnesses that would jeopardize the patient's ability to receive the regimen with reasonable safety;

12. HIV positive patients not willing to suspend HAART therapy during the treatment period of the protocol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2012
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-12-2012
Soort:	Eerste indiening

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	NL3585
NTR-old	NTR3750
Ander register	EudraCT : 2012-003141-16
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A