Zevalin-BEAM or Zevalin as consolidation in patients with transformed lymphoma.

Gepubliceerd: 25-05-2010 Laatst bijgewerkt: 13-12-2022

Consolidation of first line treatment of patients with transformed lymphoma with Zevalin of Zevalin-BEAM will prolong PFS.

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

Samenvatting

ID

NL-OMON21852

Bron
Nationaal Trial Register

Aandoening

transformed B-cell non-Hodgkin's lymphoma

Ondersteuning

Primaire sponsor: VUmc
Overige ondersteuning: initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

2-year PFS in patients with transformed non-Hodgkin’s lymphoma in CR or PR after induction chemotherapy consolidated by 90Yttrium-ibritumomab tiuxetan followed by BEAM and autologous stem cell transplantation or, in patients not eligible for AuSCT, consolidated by a single dose of 90Yttrium-ibritumomab tiuxetan.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase:

Phase II clinical trial.

Study objectives:

To estimate 2 year PFS in patients with transformed NHL after consolidation with 90Y ibritumomab tiuxetan-BEAM and AuSCT in patients eligible for AuSCT or after consolidation with a single dose of 90Y ibritumomab tiuxetan in patients not eligible for AuSCT.

Patient population:

Patients with transformed non-Hodgkin’s lymphoma in CR or PR after induction/salvage chemotherapy.

Study design:

Phase II prospective cohort study, single center, open label, non-randomized.

Duration of treatment:

Within 3 months of reaching PR or CR after induction therapy, 90Y ibritumomab tiuxetan should be administered, in case of AuSCT followed a week later by BEAM and stem cell transplantation. PET-CT for remission-assessment is done three months and two years after single dose 90Y ibritumomab tiuxetan or AuSCT.

Number of patients:

Z-BEAM followed by AuSCT: 29
90Y ibritumomab tiuxetan single dose: 29.

Adverse events:

1. Length of recovery of neutophils and platelets;

2. Immune reconstitution.

Start of recruitment: 01-05-2010;

End of recruitment: 01-05-2014.

Doel van het onderzoek

Consolidation of first line treatment of patients with transformed lymphoma with Zevalin of Zevalin-BEAM will prolong PFS.

Onderzoeksopzet

End point is progression free survival after 2 years.

Onderzoeksproduct en/of interventie

1. Consolidation of induction chemotherapy in patients eligible for stem cell transplantation with AuSCT preceeded by Zevalin-BEAM conditioning;

2. When autologous stem cell transplant is not feasible due to age, comorbidity and/or physical fitness, consolidation of induction chemotherapy in patients with transformed lymphoma not eligible for stem cell transplantation with a single dose (0,4 mCi/kg, max 32 mCi) of 90Y ibritumomab tiuxetan in order to prevent recurrence and prolong PFS.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. First diagnosis of transformation of lymphoma;

2. Histologically confirmed CD20 positive transformed B cell NHL lymphoma, according to the WHO classification 2008, stage I-IV;

3. For consolidation with AuSCT after Z-BEAM: age 18-66 years old;

4. For single dose 90Y-ibritumomab tiuxetan: older than 65 years and 18-66 years but ineligible for autologous stem cell transplantation;

5. WHO performance status of 0-2 (Appendix C);

6. Life expectancy of at least 3 months;

7. Induction treatment with R-CHOP or R-DHAP-VIM-DHAP;

8. CR defined as disappearance of all evidence of disease on PET-CT or PR defined as a reduction of tumor size of more than 50% and decreasing FDG-avidity on PET-CT after induction consisting of rituximab containing polychemotherapy. (see appendix A);

9. Absense of PET positive bulky disease after induction treatment defined as a lesion larger than 5 cm;

10. Less than 25% bone marrow involvement at the end of induction treatment (measurement in a representative bone marrow biopsy);

11. For AuSCT: Stem cells harvested: a minimum of 2 x 106 CD34+ cells/kg;

12. For single dose 90Y-ibritumomab tiuxetan: ANC ≥ 1.5 x 109/l and platelets ≥ 100 x 109/l;

13. Written informed consent obtained according to local guidelines.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known hypersensitivity to murine antibodies or proteins;

2. Presence of any other active neoplasms or history of prior malignancy, except non-melanoma skin tumours or stage 0 (in situ) cervical carcinoma during the past 5 years;

3. Patients with abnormal liver function (total bilirubin > 2.0 x ULN);

4. Presence of CNS involvement;

5. Patients with pleural effusion or ascites after induction therapy;

6. Patients who have received G-CSF or GM-CSF therapy within two weeks prior to study enrollment;

7. Patients who have received biologic therapy, immunotherapy, R-CHOP(-like) chemotherapy, surgery, or an investigational drugs less than 4 weeks prior to first day of study treatment (i.e. 90Yttrium ibritumomab tiuxetan + AuSCT) or who have not recovered from the toxic effects of such therapy;

8. Female patients who are pregnant or breast feeding, or adults of reproductive potential not employing an effective method of birth control during study treatment and for at least 12 months thereafter;

9. Known diagnosis of HIV infection;

10. Patients unwilling or unable to comply with the protocol.

Additional exclusion criteria for autologous SCT:

Unfit for high dose chemotherapy followed by autologous stem cell transplantation due to physical or mental condition.

Additional exclusion criteria for single dose 90Y-ibritumomab tiuxetan:

Patients who have received prior external beam radiotherapy to > 25% of active bone marrow (involved field or regional).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-05-2010
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	NL2213
NTR-old	NTR2338
Ander register	MEtC VUmc : 2010/079
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
none