Anti-CD20 treatment of relapsed or refractory Immune Thrombocytopenic Purpura (ITP) after first line corticosteroid treatment.

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The percentage of patients reaching CR (complete response), GR (Good Response), or MR (Moderate Response), in each treatment arm is greater than 50%.

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

Samenvatting

ID

NL-OMON23430

Bron
NTR

Verkorte titel
HOVON 64 ITP

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The response (CR/GR/MR/NR) to treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

- Study phase: Phase II

- Study objective: The first objective of the current study is to investigate the effectiveness of three different dosing schedules rituximab in refractory or relapsed ITP patients, whether or not already splenectomized. Because it is not clear whether rituximab is more effective before or after splenectomy, patients will be stratified for splenectomy. Non-splenectomized rituximab non-responders will be advised to undergo splenectomy

- Patient population: All ITP patients who have relapsed or refractory disease after first line corticosteroid treatment whether or not splenectomized, rituximab naive, age >= 18 years, WHO performance status <= 2.

- Study design: The study is designed as a combined phase II, randomized multicenter study. Patients will be stratified for splenectomy and randomized after obtaining written informed consent between: Arm A: conventional dose rituximab 375 mg/m2, 4 weekly doses; Arm B: conventional dose rituximab 375 mg/m2, 2 weekly doses (+ 2 weekly doses, dependent on response); Arm C: high dose rituximab 750 mg/m2, 2 weekly doses

- Duration of treatment: 2 to 10 weeks.

Doel van het onderzoek

The percentage of patients reaching CR (complete response), GR (Good Response), or MR (Moderate Response), in each treatment arm is greater than 50%.

Onderzoeksproduct en/of interventie

All patients will be randomized between:

- Arm A: conventional dose rituximab 375 mg/m^2, 4 weekly doses

- Arm B: conventional dose rituximab 375 mg/m^2, 2 weekly + 2 weekly doses, dependent on response

- Arm C: high dose rituximab 750 mg/m^2, 2 weekly doses.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age minimal 18 years;

2. Subjects with relapsed or refractory ITP (fulfilling the diagnostic criteria given in appendix A) and platelet numbers <30 x 10^9/l;

3. Having completed first line treatment with corticosteroids;

4. Written informed consent;

5. WHO performance status <= 2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The presence of an accessory spleen in splenectomized patients;

2. Use of anticoagulants or chemotherapy or known other disorders and/or treatments influencing the platelet number within 3 months of randomization date (tranexaminic acid (Cyklokapron®) treatment is allowed);

3. Pulsed or high dose corticosteroids, IVIG or splenectomy within 3 weeks prior to randomization. Maintenance corticosteroid therapy is allowed;

4. Prior therapy with rituximab;

5. ITP treatments (other than corticosteroids, IVIG or splenectomy) within 3 months prior to randomization (e.g. cyclosporine, vincristine). Stable treatment with non-immunosuppressive medication (i.e. danazol, dapson, vitamin C) is permitted;

6. Inadequate renal and liver function, i.e. creatinin or bilirubin >2.5 x the upper normal value;

7. Neutrophil count <1.5 x 10^9/l and hemoglobin level <6.2 mmol/l;

8. Active bleeding (defined by grade 3 or 4 according to NCI CTCAE v3.0);

9. Pregnant or lactating;

10. Systemic infections: active viral infections, including HIV;

11. Seriously immunocompromised patients;

12. Systemic autoimmune disorders (e.g. Systemic lupus erythematosus (SLE));

13. Current malignant disease;

14. Any experimental therapy within 30 days prior to randomization.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	31-08-2005
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	NL174
NTR-old	NTR211
Ander register	: HO64
ISRCTN	ISRCTN16619820

Resultaten

Samenvatting resultaten
N/A