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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23430

Source
NTR

Brief title
HOVON 64 ITP

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Need for emergency treatment (platelet count <10 or hemorrhagic diathesis, hemorrhage/bleeding defined by grade 3 or 4 according to NCI CTCAE v3.0);

2. Time to treatment failure/relapse.

Study description

Background summary

- 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.

Study objective

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	31-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL174
NTR-old	NTR211
Other	: HO64
ISRCTN	ISRCTN16619820

Study results

Summary results
N/A