

Anti-CD20 treatment of relapsed or refractory immune thrombocytopaenic purpura (ITP) after first line corticosteroid treatment

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2008	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

HO64

Study information

Scientific Title

Acronym

HOVON 64 ITP

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Immune thrombocytopaenic purpura (ITP)

Interventions

All patients will be randomised between:

Arm A: conventional dose rituximab 375 mg/m², 4 weekly doses

Arm B: conventional dose rituximab 375 mg/m², 2 weekly + 2 weekly doses, dependent on response

Arm C: high dose rituximab 750 mg/m², 2 weekly doses

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rituximab

Primary outcome(s)

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

Key secondary outcome(s)

1. Need for emergency treatment (platelet count less than 10 or haemorrhagic diathesis, haemorrhage/bleeding defined by grade 3 or 4 according to NCI CTCAE v3.0)
2. Time to treatment failure/relapse

Completion date

01/05/2008

Eligibility

Key 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 less than $30 \times 10^9/l$
3. Having completed first line treatment with corticosteroids
4. Written informed consent
5. World Health Organization (WHO) performance status less than or equal to 2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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 randomisation date (tranexaminic acid [Cyklokapron®] treatment is allowed)
3. Pulsed or high dose corticosteroids, IVIG or splenectomy within 3 weeks prior to randomisation. Maintenance corticosteroid therapy is allowed.
4. Prior therapy with rituximab
5. ITP treatments (other than corticosteroids, IVIG or splenectomy) within 3 months prior to randomisation (e.g. cyclosporin, vincristine). Stable treatment with non-immunosuppressive medication (i.e. danazol, dapson, vitamin C) is permitted.
6. Inadequate renal and liver function, i.e. creatinine or bilirubin greater than 25 x the upper normal value
7. Neutrophil count less than $15 \times 10^9/l$ and haemoglobin level less than 62 mmol/l
8. Active bleeding (defined by grade 3 or 4 according to National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE] v3.0)
9. Pregnant or lactating
10. Systemic infections: active viral infections, including human immunodeficiency virus (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 randomisation

Date of first enrolment

01/09/2005

Date of final enrolment

01/05/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DE

Sponsor information

Organisation

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (The Netherlands) - Data Centre

ROR

<https://ror.org/056kpx27>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes