

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

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| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>14/11/2008       | <b>Condition category</b><br>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

## Study website

<http://www.hovon.nl>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**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/m<sup>2</sup>, 4 weekly doses

Arm B: conventional dose rituximab 375 mg/m<sup>2</sup>, 2 weekly + 2 weekly doses, dependent on response

Arm C: high dose rituximab 750 mg/m<sup>2</sup>, 2 weekly doses

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Rituximab

**Primary outcome measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/09/2005

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

150

**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

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.hovon.nl>

**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****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration