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

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/11/2008	Haematological Disorders	[ ] 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

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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^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

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 x 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 x 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
Erasmus Medical Centre
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Sponsor type
Research organisation

Website
http://www.hovon.nl

ROR
https://ror.org/056kpdx27

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