A RANDOMIZED, OPEN-LABEL, MULTI-CENTRE STUDY TO EVALUATE PATIENT PREFERENCE WITH SUBCUTANEOUS ADMINISTRATION OF RITUXIMAB VERSUS INTRAVENOUS RITUXIMAB IN PREVIOUSLY UNTREATED PATIENTS WITH CD20+ DIFFUSE LARGE B-CELL LYMPHOMA OR CD20+ FOLLICULAR NON-HODGKIN*S LYMPHOMA GRADES 1, 2 OR 3A

Published: 02-11-2012
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To evaluate the proportion of patients indicating an overall preference via a Patient Preference Questionnaire (PPQ) for either the subcutaneous (SC) or the intravenous (IV) route of rituximab administration.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON40118

Source
ToetsingOnline

Brief title
PrefMab Study

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
Non-Hodgkin-Lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche Nederland B.V.

Intervention

Keyword: Non Hodgkin Lymphoma, Preference, Rituximab, Subcutaneous/Intraveneous

Outcome measures

Primary outcome

The primary objective for this study is as follows:

To evaluate the proportion of patients indicating an overall preference via a

Patient Preference Questionnaire (PPQ) for either the SC or the IV route of

rituximab administration.

Secondary outcome

The secondary objectives for this study are as follows:

* To evaluate and compare the methods of rituximab administration (SC vs. IV)

in terms of:

* Rituximab administration time defined as the time from start to end of the

rituximab SC injection or from start to end of the rituximab IV infusion

Patient-assessed satisfaction and convenience using the Cancer Therapy

Satisfaction Questionnaire (CTSQ) and Rituximab Administration Satisfaction

Questionnaire (RASQ)

*Immunogenicity (anti-rituximab and anti-rHuPH20 antibodies and the

associated rituximab concentration level at each anti-rituximab sampling

time point).

*To evaluate efficacy of rituximab SC in terms of:

*complete response rate (CR) including complete response unconfirmed (CRu), 4-8

weeks after the last dose of induction treatment

*EFS

*DFS

*PFS

*overall survival (OS).

The safety objectives for this study are to evaluate the safety of rituximab SC

and rituximab IV in patients with DLBCL or follicular NHL, focusing on SAEs,

Grade * 3 AEs, and Grade * 3 IIRRs according to NCI CTCAE version 4.0.

Study description

Background summary

Roche is investigating the subcutaneous injection into the skin of rituximab (referred to as subcutaneous rituximab) compared to the intravenous rituximab administration. Compared to iv administration, the sc injection will only take 5 to 7 minutes. This simple SC injection will allow the time of patient stay to reduce significantly compared to IV administration. This reduction will also apply to hospital burden associated with IV administration. Additionally, Roche expects that the subcutaneous administration will increase patient satisfaction, ease of administration and treatment compliance.

Study objective

To evaluate the proportion of patients indicating an overall preference via a

Patient Preference Questionnaire (PPQ) for either the subcutaneous (SC) or the intravenous (IV) route of rituximab administration.

Study design

This is a Phase IV, prospective, multi-centre, multinational, open-label randomized study in approximately 900 adult patients with previously untreated CD20+ DLBCL or CD20+ follicular NHL. Eligible patients will be randomized to Treatment Arm A or Arm B (see Figure 1) using a centralized interactive voice/web response system (IVRS/IWRS) with a 1:1 ratio. Patients will be stratified (see protocol page 44). Patients randomized to Arm A will receive 1 cycle of rituximab IV then 3 cycles of rituximab SC followed by 4 cycles of rituximab IV after interim staging. Patients randomized to Arm B will receive 4 cycles of rituximab IV, followed by 4 cycles of rituximab SC after interim staging. For information regarding Interim staging, see protocol page 44.
Study treatment in both groups will consist of 8 cycles of rituximab administered in combination with CHOP, CVP or bendamustine, as per standard local practice. During study treatment, patients will be assessed for safety and efficacy as detailed in the Schedule of Assessments (see protocol appendix 1).
After induction treatment has been completed after Cycle 8, patients will be followed every 3 months for the first two years and then every 6 months until the end of the study, as detailed in the Schedule of Assessments (appendix 1 protocol)

Intervention

Study treatment in both groups will consist of 8 cycles of rituximab administered in combination with CHOP, CVP or bendamustine, as per standard local practice.

CHOP: cyclophosphamide, oncovine (vincristine), doxorubicin, prednisone.
CVP: cyclophosphamide, oncovine (vincristine), prednisone

Arm A:
Patients randomized to Arm A will receive 1 cycle of rituximab IV then 3 cycles of rituximab SC followed by 4 cycles of rituximab IV after interim staging.

Arm B:
Patients randomized to Arm B will receive 4 cycles of rituximab IV, followed by 4 cycles of rituximab SC after interim staging.

Rituximab SC formulation: 11.7 ml - 1400 mg (independent of the BSA)
Rituximab IV: 375 mg/mE2 BSA (10 mg/ml)

For information regarding Interim staging, see protocol page 44.

Study burden and risks

See secties E4, E6 and E9

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Signed, written Informed consent form;2. Age * 18 and * 80 years at time of randomization ;3. Histologically confirmed, previously untreated CD20+ DLBCL or CD20+ follicular NHL Grade 1, 2 or 3a, according to the WHO classification system;4. An IPI score of 1-4 or IPI score of 0 with bulky disease, defined as one lesion * 7.5 cm, or FLIPI (low, low-intermediate, high-intermediate, high) ;5. At least one bi-dimensionally measurable lesion defined as * 1.5 cm in its largest dimension on CT scan;6. Eastern Cooperative Oncology Group (ECOG) performance

status * 3.

Exclusion criteria

1. Transformed lymphoma or FL IIIB ;2. Primary CNS lymphoma, blastic variant of mantle-cell lymphoma, histologic evidence of transformation to a Burkitt lymphoma, primary mediastinal DLBCL, primary effusion lymphoma, primary cutaneous DLBCL or primary DLBCL of the testis;3. History of other malignancy that could affect compliance with the protocol or interpretation of results. This includes a malignancy that has been treated but not with curative intent, unless the malignancy has been in remission without treatment for * 5 years prior to enrolment. Note: Patients with a history of curatively treated basal or squamous cell carcinoma or melanoma of the skin or in situ carcinoma of the cervix are eligible for the study.;4.Prior therapy for DLBCL or follicular NHL, with the exception of nodal biopsy or local irradiation;5.Prior treatment with cytotoxic drugs (with the exclusion of methotrexate for CNS prophylaxis in DLBCL) or rituximab for another condition (e.g., rheumatoid arthritis) or prior use of an anti-CD20 antibody;6.Prior use of any monoclonal antibody within 3 months prior to randomization ;See for all exclusion criteria: protocol section 4.1.2, page 51-52.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2013
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MabThera IV
Generic name:	Rituximab IV
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	MabThera SC
Generic name:	Rituximab SC

Ethics review

Approved WMO Date:	02-11-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-01-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-05-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-09-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2014
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2012-003230-17-NL
Other	Het onderzoek is onder het EudraCT nummer terug te vinden op www.rochetrials.com
CCMO	NL42241.060.12