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Radioimmunotherapy with 90Y Ibritumumab Tiuxetan in B-cell CD20+ indolent non-Hodgkin Lymphoma

Submission date
17/03/2013

Recruitment status
No longer recruiting

Registration date
10/04/2013

Overall study status
Completed

Last Edited
08/01/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Treatment with 90YIbritumomab/tiuxetan (90Y-IT) in CD20+ for non Hodgkin lymphoma (NHL) patients is safe and effective. We have reviewed our hospital database to analyse the outcomes of CD20+ NHL patients over 65 years old treated with 90Y-IT

Who can participate?
Patients diagnosed with CD20+ indolent NHL.

What does the study involve?
To analyze the results of therapy with 90Y-Ibritumomab/tiuxetan in clinical practice prescription.

What are the possible benefits and risks of participating?
90Y-IT has demonstrated high efficacy and safety in the therapy of CD20+ indolent NHL patients. We want to analyse these aspects in patients treated over 65 years old and to evaluate safety, survival and comorbidities in the long term.

Where is the study run from?
The Miguel Servet University Hospital, Zaragoza (Spain).

When is the study starting and how long is it expected to run for?
The study started in September 2005 when the first patient received therapy with 90Y-IT in the Miguel Servet University Hospital.

Who is funding the study?
The Foundation for the Study of Hematology in Aragon (FEHHA)

Who is the main contact?
Dr Pilar Giraldo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
RIT-002

Study information

Scientific Title
Radioimmunotherapy with 90Y Ibritumumab Tiuxetan in B-cell CD20+ indolent non-Hodgkin Lymphoma: A retrospective study

Acronym
RIT

Study objectives
Radioimmunotherapy (RIT) emerged as an option after Mo-Ab success, combining the selectivity of the anti CD-20 immunotherapy with an attached radioisotope, making possible the delivery of radiation exactly within the tumor burden. The previous phase III randomized study that compared 90Y-IT with Rituximab immunotherapy in relapsed or refractory low-grade follicular or transformed CD20+ NHL showed significant ORR for the 90Y-IT group vs the Rituximab group. In addition the results of the phase III randomized study of 90Y-IT as front-line consolidation, the First-line Indolent Trial (FIT) published in 2008, showed that 90Y-IT consolidation significantly prolonged median Progression Free Survival (PFS) after a median of 3.5 years of observation, and converted 77% of Partial Response (PR) after induction into CR, resulting in a CR rate of 87% with low associated toxicity.

We incorporated RIT with 90Y Ibritumumab Tiuxetan in B-cell CD20+ indolent non-Hodgkin Lymphoma since 2005 according an a clinical protocol conducted by a multidisciplinary team formed by clinical hematologists, nuclear medicine physicians, radiopharmacy physicians and nurses in the Miguel Servet University Hospital at Saragossa, Spain. In 2007 the therapeutic inclusion was extended as consolidation after first-line chemotherapy in patients with complete or partial response confirmed by PET/CT. All patients had been treated and follow-up with the same criteria and now we want to analyze retrospectively the results after long term follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Comite de estudios de investigación clínica de Aragón (CEICA),

Study design
Interventional non-randomised retrospective study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
B-cell CD20+ indolent non-Hodgkin Lymphoma

Interventions
A retrospective study based in a clinical protocol conducted by a multidisciplinary team comprising clinical hematologists, nuclear medicine physicians, radiopharmacists, and nurses at MSUH

Therapy with 90-YIbritumomab/tiuxetan in relapsed and refractory indolent B-cell NHL and in consolidation after first-line immuno- or chemoimmunotherapy.

The study is open in one arm and all patients received an intravenously infusion of Rituximab on day 1 at dose of 250 mg/m2 and a second dose of Rituximab 250 mg/m2 on day 7 followed by weight-based dose of 90Y-IT administered as slow intravenous push over 10 minutes within the next 4 hours of Rituximab infusion.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
90Y Ibritumumab Tiuxetan

Primary outcome(s)
Response assessment was made 12 weeks after treatment

PET/CT scan was performed in all cases and response criteria used were the same as the International Working Group (IWG). and classified as Complete Response (CR), Partial Response (PR) and no response (NR).

Key secondary outcome(s))

1. Time to Progression (TTP)
2. Overall Response (OR) and OS in all patients.
3. We also registered side effects, with special emphasis in myelotoxicity and emerging second neoplasms.

TTP and OS were calculated from the date of 90Y-IT therapy until disease progression or death. All eligible patients were accepted by the clinical committee and included into the analysis.

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Adults patients with an excisional biopsy-confirmed diagnosis of CD20+ F-NHL grade 1, 2, or 3a according to the revised WHO classification system
2. ECOG performance status ≤ 2
3. Absolute neutrophil count (ANC) ≥ 1,500/μL
4. Absolute platelet count (APC) ≥ 100,000/μL
5. Bone marrow total lymphocytes ≤ 25% by morphological counting
6. Serum bilirubin ≤ 2.0mg/dL and serum creatinine ≤ 2.0mg/dL
7. All patients were requested to sign an informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Presence of any other malignancy or history of prior malignancy within 5 years of study entry. This does not apply to-non melanoma skin tumors and in situ cervical cancer.
2. Prior radioimmunotherapy
3. Presence of primary central nervous system (CNS) lymphoma at first diagnosis
4. Known seropositivity for hepatitis C virus (HCV) or hepatitis B surface antigen (HbsAg).
5. Known history of HIV infection
6. Abnormal liver function: total bilirubin > 2 × ULN unless secondary to Gilbert disease.
7. Abnormal renal function: serum creatinine > 2.0 × ULN
8. Ongoing toxic effects of chemotherapy > grade 2 and expected to interfere with Zevalin® treatment.

Date of first enrolment
01/09/2005

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
Spain

Study participating centre
Haematology Department
Zaragoza
Spain
50009

Sponsor information

Organisation
Foundation for the Study of hematology in Aragon [Fundación para el Estudio de la Hematologia y Hemoterapia en Aragón](FEHHA)

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for the Study of hematology in Aragon [Fundación para el Estudio de la Hematologia y Hemoterapia en Aragón](FEHHA) (Spain)

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?
	results				

Results article	01/12/2014	Yes	No