ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 10/21/2014

ClinicalTrials.gov ID: NCT00770562

Study Identification

Unique Protocol ID:	ML18542
Brief Title:	A Study Evaluating the Addition of MabThera (Rituximab) to Standard Treatment in Patients With Idiopathic Thrombocytopenic Purpura (ITP)
Official Title:	A Randomized, Open-label Study of First-line Treatment With Dexamethasone or Dexamethasone Plus MabThera on Sustained Treatment Response in Adult Patients With Idiopathic Thrombocytopenic Purpura
Secondary IDs:	

Study Status

Record Verification:	October 2014
Overall Status:	Completed
Study Start:	July 2005
Primary Completion:	July 2008 [Actual]
Study Completion:	July 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: Unknown Board Name: Comitato Etico Indipendente Facolta di Medicina e Chirurgia Universita degli Studi di Udine Board Affiliation: Policlinico Universitario a gestione Diretta di Udine Phone: ++39 0432 559819 Email: comitato.etico@uniud.it
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Italy:AIFA

Study Description

Brief Summary:	This study will compare the efficacy, safety, and pharmacokinetics of standard treatment versus standard treatment plus MabThera in patients with ITP. The anticipated time on study treatment is <3 months, and the target sample size is 100-500 individuals.
Detailed Description:	

Conditions

Conditions:	Idiopathic Thrombocytopenic Purpura
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	103 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Dexamethasone Participants received 40 milligrams (mg) dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4). Participants in this treatment arm who failed to achieve a sustained response and had a platelet count of less than or equal to (≤)20 x 10^9 platelets per liter (L; from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg per square meter (mg/m^2), intravenously (IV), with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.	Drug: Dexamethasone
Experimental: Dexamethasone plus Rituximab Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants with platelets less than (<) 20 x10^9/L or with active bleeding could have also received an additional treatment course of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with immunoglobulin (IgG) IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.	Drug: rituximab Other Names: • MabThera/Rituxan Drug: Dexamethasone

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- adult patients >=18 years of age;
- untreated ITP.

Exclusion Criteria:

- ITP with relapse;
- positive test result for HIV or hepatitis B or C;
- active infection requiring systemic therapy;
- malignancy within 3 years before study.

Contacts/Locations

Study Officials: Clinical Trials
Study Chair
Hoffmann-La Roche

Locations: Italy
Taranto, Italy, 74100

Pescara, Italy, 65100

Palermo, Italy, 90146

Roma, Italy, 00133

Napoli, Italy, 80131

Milano, Italy, 20162

Siena, Italy, 53100

Pavia, Italy, 27100

Roma, Italy, 00168

Cagliari, Italy, 09121

Verona, Italy, 37130

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Genova, Italy, 16132

Pesaro, Italy, 61100

Ravenna, Italy, 48100

Bologna, Italy, 40138

Brescia, Italy, 25123

Padova, Italy, 35128

Cuneo, Italy, 12100

Bari, Italy, 70124

Roma, Italy, 00161

Udine, Italy, 33100

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Arm A: Dexamethasone	Participants received 40 milligrams (mg) dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4). Participants in this treatment arm who failed to achieve a sustained response and had a platelet count of less than or equal to (≤)20 x 10^9 platelets per liter (L; from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg per square meter (mg/m^2), intravenously (IV), with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.
Arm B: Dexamethasone + Rituximab	Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants with platelets less than (<) 20 x10^9/L or with active bleeding could have also received an additional treatment course of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with immunoglobulin (IgG) IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.

Overall Study

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab
Started	53	50
Completed	52	49
Not Completed	1	1
Did not take treatment	1	1

Baseline Characteristics

Reporting Groups

	Description
Arm A: Dexamethasone	Participants received 40 mg dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4). Participants in this treatment arm who failed to achieve a sustained response and had a platelet count of ≤20 x 10^9 platelets per liter (L; from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.
Arm B: Dexamethasone + Rituximab	Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg per square meter (mg/m^2), IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants with platelets <20 x10^9/L or with active bleeding could have also received an additional treatment course of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with IgG IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.

Baseline Measures

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Total
Number of Participants	52	49	101
Age, Continuous [units: years] Mean (Standard Deviation)	47 (19)	49 (16)	48.41 (18.03)
Gender, Male/Female [1] [units: participants]			
Female	33	27	60
Male	19	22	41

[1] Two participants were not accessed because they did not take the study drug after being randomized.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With a Sustained Response
Measure Description	Sustained response defined as a platelet count of greater than or equal to (≥) 50x10^9/L at 6 months (Week 24) after the initial treatment. Participants failing therapy before Month 6 (Week 24) and treated in other ways were considered failures.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population includes all participants who were randomized, who received at least (<) 1 dose of study medication, and who had at least 1 follow-up contact.

Reporting Groups

	Description
Arm A: Dexamethasone	Participants received 40 mg dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4). Participants in this treatment arm who failed to achieve a sustained response and had a platelet count of ≤20 x 10^9/L (from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.
Arm B: Dexamethasone + Rituximab	Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants with platelets <20 x10^9/L or with active bleeding could have also received an additional treatment course of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with IgG IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.

Measured Values

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab
Number of Participants Analyzed	52	49
Percentage of Participants With a Sustained Response [units: percentage of participants]	36	63

Statistical Analysis 1 for Percentage of Participants With a Sustained Response

Statistical Analysis Overview	Comparison Groups	Arm A: Dexamethasone, Arm B: Dexamethasone + Rituximab
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.004
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Initial Response
Measure Description	Initial response was defined as an increase in platelet count of ≥50x10^9/L by Day 30 (Week 4) after the start of treatment in either treatment arm.
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

ITT population; excluding participants who received additional steroid therapy or IV Ig course during the first month of therapy.

Reporting Groups

	Description
Arm A: Dexamethasone	Participants received 40 mg dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4). Participants in this treatment arm who failed to achieve a sustained response and had a platelet count of ≤20 x 10^9/L (from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.

	Description
Arm B: Dexamethasone + Rituximab	Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants with platelets <20 x10^9/L or with active bleeding could have also received an additional treatment course of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with IgG IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.

Measured Values

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab
Number of Participants Analyzed	44	25
Percentage of Participants With an Initial Response [units: percentage of participants]	27	68

Statistical Analysis 1 for Percentage of Participants With an Initial Response

Statistical Analysis Overview	Comparison Groups	Arm A: Dexamethasone, Arm B: Dexamethasone + Rituximab
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Initial Complete Response
Measure Description	Initial complete response was defined as an increase in platelet count of ≥100x10^9/L by Day 30 (Week 4) after the initiation of treatment in either treatment arm.
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

ITT population; excluding participants who received additional steroid therapy or IV Ig course during the first month of therapy.

Reporting Groups

	Description
Arm A: Dexamethasone	Participants received 40 mg dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4). Participants in this treatment arm who failed to achieve a sustained response and had a platelet count of ≤20 x 10^9/L (from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.
Arm B: Dexamethasone + Rituximab	Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants with platelets <20 x10^9/L or with active bleeding could have also received an additional treatment course of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with IgG IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.

Measured Values

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab
Number of Participants Analyzed	44	25
Percentage of Participants With an Initial Complete Response [units: percentage of participants]	23	48

Statistical Analysis 1 for Percentage of Participants With an Initial Complete Response

Statistical Analysis Overview	Comparison Groups	Arm A: Dexamethasone, Arm B: Dexamethasone + Rituximab
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.015
	Comments	[Not specified]
	Method	Fisher Exact

	Comments	[Not specified]

Reported Adverse Events

Time Frame	6 months
Additional Description	[Not specified]

Reporting Groups

	Description
Arm A: Dexamethasone	Participants received 40 mg dexamethasone, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4).
Arm B: Dexamethasone + Rituximab	Participants received dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28.
Salvage Therapy	Nonresponsive (failed to achieve a sustained response) participants from Arm A (dexamethasone monotherapy) who had a platelet count of ≤20 x 10^9/L (from Day 30 up to end of 6 months) were treated with salvage treatment of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV, with premedication of oral acetaminophen 500 mg and chlorpheniramine 10 mg IV on Days 7, 14, 21, and 28. Nonresponsive participants from Arm B (dexamethasone + rituximab) with platelets <20 x10^9/L or with active bleeding were treated with salvage therapy of dexamethasone 40 mg, orally, once per day for 4 consecutive days (Days 1, 2, 3, and 4) and rituximab 375 mg/m^2, IV on Days 7, 14, 21, and 28 administered with IgG IV (at investigator discretion) and/or low/medium dose steroids (at investigator discretion) on Days 7, 14, 21, and 28.

Serious Adverse Events

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/52 (1.92%)	3/49 (6.12%)	3/27 (11.11%)
Blood and lymphatic system disorders			
Hemorrhage syndrome [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Hemorrhagic syndrome and low platelet [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Platelet count decreased [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Cardiac disorders			

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Supraventricular tachycardia [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Infections and infestations			
Interstitial pneumonia [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Injury, poisoning and procedural complications			
Rib fracture [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Nervous system disorders			
Convulsion [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Seizure [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
TIA [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA v.3.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	25/52 (48.08%)	37/49 (75.51%)	18/27 (66.67%)
Blood and lymphatic system disorders			
Anaemia [A] *	2/52 (3.85%)	2/49 (4.08%)	1/27 (3.7%)
Iron deficiency anaemia [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Leukopenia [A] *	0/52 (0%)	0/49 (0%)	2/27 (7.41%)
Cardiac disorders			
Arrhythmia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Bradycardia [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Eye disorders			
Conjunctival haemorrhage [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Conjunctivitis [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Gastrointestinal disorders			
Abdominal pain [A] *	1/52 (1.92%)	1/49 (2.04%)	0/27 (0%)
Abdominal pain upper [A] *	1/52 (1.92%)	7/49 (14.29%)	2/27 (7.41%)
Constipation [A] *	1/52 (1.92%)	1/49 (2.04%)	2/27 (7.41%)
Diarrhoea [A] *	0/52 (0%)	5/49 (10.2%)	0/27 (0%)
Dyspepsia [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Dysphagia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Gastritis [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Gingival bleeding [A] *	1/52 (1.92%)	3/49 (6.12%)	1/27 (3.7%)
Haemorrhoids [A] *	1/52 (1.92%)	0/49 (0%)	1/27 (3.7%)
Vomiting [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
General disorders			
Adverse drug reaction [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Asthenia [A] *	2/52 (3.85%)	5/49 (10.2%)	0/27 (0%)
Chest pain [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Chills [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Fatigue [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Gravitational oedema [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Hyperpyrexia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Malaise [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Mucosal hyperaemia [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Mucosal inflammation [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Oedema peripheral [A] *	2/52 (3.85%)	0/49 (0%)	0/27 (0%)
Pyrexia [A] *	1/52 (1.92%)	10/49 (20.41%)	5/27 (18.52%)
Hepatobiliary disorders			
Biliary colic [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Immune system disorders			
Hypersensitivity [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Infections and infestations			
Acute sinusitis [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Bronchitis acute [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Cystitis [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Folliculitis [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Gastroenteritis [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Helicobacter infection [A] *	1/52 (1.92%)	2/49 (4.08%)	0/27 (0%)
Herpes simplex [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Herpes zoster [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Influenza [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Lung infection [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Nasopharyngitis [A] *	2/52 (3.85%)	4/49 (8.16%)	0/27 (0%)
Pharyngitis [A] *	1/52 (1.92%)	2/49 (4.08%)	0/27 (0%)

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Tinea versicolour [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Tooth abscess [A] *	0/52 (0%)	2/49 (4.08%)	2/27 (7.41%)
Tracheitis [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Upper respiratory tract infection [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Urinary tract infection [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Injury, poisoning and procedural complications			
Injury [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Traumatic haematoma [A] *	1/52 (1.92%)	1/49 (2.04%)	0/27 (0%)
Traumatic haemorrhage [A] *	1/52 (1.92%)	1/49 (2.04%)	0/27 (0%)
Investigations			
Aspartate aminotransferase increased [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Blood amylase increased [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Blood pressure abnormal [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Blood pressure increased [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Gamma-glutamyltransferase increased [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Lipase increased [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Oxygen saturation decreased [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Platelet count decreased [A] *	2/52 (3.85%)	0/49 (0%)	2/27 (7.41%)
Transaminases increased [A] *	3/52 (5.77%)	2/49 (4.08%)	0/27 (0%)
Metabolism and nutrition disorders			
Fluid retention [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Hypercholesterolaemia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hyperglycaemia [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Hyperuricaemia [A] *	1/52 (1.92%)	1/49 (2.04%)	0/27 (0%)
Hypokalaemia [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] *	0/52 (0%)	1/49 (2.04%)	1/27 (3.7%)
Arthritis [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Back pain [A] *	1/52 (1.92%)	1/49 (2.04%)	2/27 (7.41%)
Bone pain [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Muscle spasms [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Musculoskeletal discomfort [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Myalgia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Neck pain [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Osteoarthritis [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Pain in extremity [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Nervous system disorders			
Cognitive disorder [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Dizziness [A] *	1/52 (1.92%)	1/49 (2.04%)	1/27 (3.7%)
Headache [A] *	3/52 (5.77%)	6/49 (12.24%)	2/27 (7.41%)
Neuralgia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Transient ischaemic attack [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Psychiatric disorders			
Anxiety [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Depression [A] *	0/52 (0%)	2/49 (4.08%)	0/27 (0%)
Insomnia [A] *	2/52 (3.85%)	1/49 (2.04%)	0/27 (0%)
Renal and urinary disorders			
Dysuria [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Nephrolithiasis [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Renal colic [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Renal failure acute [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Strangury [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Reproductive system and breast disorders			
Menorrhagia [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Metrorrhagia [A] *	1/52 (1.92%)	2/49 (4.08%)	0/27 (0%)
Ovarian cyst [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Prostatitis [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Respiratory, thoracic and mediastinal disorders			
Asthma [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Cough [A] *	5/52 (9.62%)	6/49 (12.24%)	0/27 (0%)
Dyspnoea [A] *	0/52 (0%)	3/49 (6.12%)	0/27 (0%)
Dyspnoea exertional [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Epistaxis [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Hiccups [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)

	Arm A: Dexamethasone	Arm B: Dexamethasone + Rituximab	Salvage Therapy
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pharyngolaryngeal pain [A] *	1/52 (1.92%)	1/49 (2.04%)	0/27 (0%)
Productive cough [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Tonsillar disorder [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Skin and subcutaneous tissue disorders			
Dermatitis [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Erythema [A] *	1/52 (1.92%)	2/49 (4.08%)	1/27 (3.7%)
Periorbital oedema [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Petechiae [A] *	4/52 (7.69%)	0/49 (0%)	1/27 (3.7%)
Pruritus [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Psoriasis [A] *	1/52 (1.92%)	0/49 (0%)	0/27 (0%)
Purpura [A] *	2/52 (3.85%)	0/49 (0%)	0/27 (0%)
Skin discolouration [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)
Vascular disorders			
Arteriosclerosis [A] *	0/52 (0%)	0/49 (0%)	1/27 (3.7%)
Hypertension [A] *	1/52 (1.92%)	1/49 (2.04%)	0/27 (0%)
Hypotension [A] *	1/52 (1.92%)	1/49 (2.04%)	1/27 (3.7%)
Phlebitis superficial [A] *	0/52 (0%)	1/49 (2.04%)	0/27 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA v.3.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights

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