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- ☑ Trial identification
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- ☑ Sponsor identification
- ☑ Information on the IMP/placebo
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- Ergebnisberichte
Bei dem nachfolgenden Ergebnisbericht handelt es sich um Daten des pharmazeutischen Unternehmers, der Inhaber der Zulassung des Test-Pruefpraeparates ist, oder des Sponsors
2010-022058-18

2/1 von 1 BfArM: Datenbank Clinical Trials (PCT00) © BMG

2010-022058-18 A PHASE II STUDY TO INVESTIGATE THE EFFICACY OF CYCLOPHOSPHAMIDE AS SOLE GRAFT-VERSUS-HOST-PROPHYLAXIS AFTER ALLOGENEIC STEM CELL TRANSPLANTATION (OCTET-CY)

Entry in CT-Database (OFF):

Trial identification

EudraCT number:	2010-022058-18
Full title of the trial:	A PHASE II STUDY TO INVESTIGATE THE EFFICACY OF CYCLOPHOSPHAMIDE AS SOLE GRAFT-VERSUS-HOST-PROPHYLAXIS AFTER ALLOGENEIC STEM CELL TRANSPLANTATION (OCTET-CY)
Abbreviated title:	OCTET-CY
Sponsor's protocol code number:	Uni-Koeln-1430
Trial part of a PIP:	Not answered

Workflow information of National Competent Authority

Zuständige Behörde:	BfArM
Bescheiddatum Bundesoberbehörde:	20110215
Bescheidart Bundesoberbehörde:	Genehmigung
Bescheiddatum Ethikkommission:	20110216
Bescheidart Ethikkommission:	positiv
Stand der Studie/Art:	Beendigung
Datum/Ende der Studie in Deutschland:	20131118

Sponsor identification

Sponsor

Status of the Sponsor: Non-Commercial

University of Cologne
Germany

Information on the investigational medicinal product(s)/placebo(s)

1: Cyclophosphamide (PR1)

Product role: Test

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation:	Y
Trade name:	ENDOXAN 1g
Name of marketing authorisation holder:	Baxter Oncology
Marketing authorisation granted by:	Germany

IMP - Description of the investigational medicinal product

Product name:	Cyclophosphamide
Pharmaceutical form:	Powder for solution for infusion
Specific paediatric formulation:	Not answered
Route of administration:	Intravenous use

Active substance-INN / proposed INN:	CYCLOPHOSPHAMIDE
Concentration type:	exact number

Concentration number part 1: 1
Concentration unit: g gram(s)

IMP - Type of the IMP

Active substance origin - chemical: Y

IMP - Regulatory information

Orphan drug designation in the Community: N

2: Cyclophosphamide (PR2)

Product role: Test

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation: Y
Trade name: ENDOXAN 100mg
Name of marketing authorisation holder: Baxter Oncology
Marketing authorisation granted by: Germany

IMP - Description of the investigational medicinal product

Product name: Cyclophosphamide
Pharmaceutical form: Powder for solution for infusion
Specific paediatric formulation: Not answered
Route of administration: Intravenous use

Active substance-INN / proposed INN: CYCLOPHOSPHAMIDE
Concentration type: exact number
Concentration number part 1: 100
Concentration unit: mg milligram(s)

IMP - Type of the IMP

Active substance origin - chemical: Y

IMP - Regulatory information

Orphan drug designation in the Community: N

3: Cyclophosphamide (PR3)

Product role: Test

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation: Y
Trade name: ENDOXAN 200mg
Name of marketing authorisation holder: Baxter Oncology
Marketing authorisation granted by: Germany

IMP - Description of the investigational medicinal product

Product name: Cyclophosphamide
Pharmaceutical form: Powder for solution for infusion
Specific paediatric formulation: Not answered
Route of administration: Intravenous use

Active substance-INN / proposed INN: CYCLOPHOSPHAMIDE
Active substance - CAS number: 50180
Concentration type: exact number
Concentration number part 1: 200
Concentration unit: mg milligram(s)

IMP - Type of the IMP

Active substance origin - chemical: Y

IMP - Regulatory information

Orphan drug designation in the N

Community:

4: Cyclophosphamide (PR4)

Product role: Test

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation: Y
Trade name: ENDOXAN 500mg
Name of marketing authorisation holder: Baxter Oncology
Marketing authorisation granted by: Germany

IMP - Description of the investigational medicinal product

Product name: Cyclophosphamide
Pharmaceutical form: Powder for solution for infusion
Specific paediatric formulation: Not answered
Route of administration: Intravenous use

Active substance-INN / proposed INN: CYCLOPHOSPHAMIDE
Active substance - CAS number: 50180
Concentration type: exact number
Concentration number part 1: 500
Concentration unit: mg milligram(s)

IMP - Type of the IMP

Active substance origin - chemical: Y

IMP - Regulatory information

Orphan drug designation in the Community: N

Placebo - Information on the placebo(s)

Placebo in this trial:

Information on the trial

General information on the trial

Medical condition: Patients with multiple myeloma, Non-Hodgkin's lymphoma or Hodgkins disease having undergone allogeneic stem cell transplantation

MedDRA:	MedDRA version code	MedDRA level	MedDRA classification code	MedDRA term
	12.1	LLT	10028566	Myeloma
	12.1	LLT	10020206	Hodgkin's disease
	12.1	LLT	10029547	Non-Hodgkin's lymphoma

Rare disease: N

Main objective of the trial: To assess the efficacy of post-transplantation cyclophosphamide as single-agent GvHD prophylaxis after allogeneic hematopoietic stem cell transplantation in patients with multiple myeloma or lymphoma and to describe the influence of the modified immunosuppression concept on relapse rates, minimal residual disease, immune reconstitution and chimerism.Primary end point: (bullit) Number of patients not requiring any additional immunosuppressive treatment until day 100 after allogeneic transplantation

Secondary objectives of trial: Secondary end point: (bullit) Cumulative incidence and severity of acute GvHD (bullit) Cumulative incidence of relapse (bullit) Non-relapse-mortality at day +28 and +100 (bullit) Overall survival at day +100 (bullit) Haematopoietic reconstitution (bullit) Donor chimerism (bullit) Immune reconstitution

Sub-study: N

Principal inclusion criteria: (bullit) Written informed consent (bullit) Patients with multiple myeloma, Non-Hodgkin's lymphoma or Hodgkin's disease after allogeneic stem cell transplantation with reduced intensity conditioning (bullit) Transplantation of stem cells from one of the following donors:-HLA-identical sibling donor (SIB)-HLA-matched unrelated donor (MUD)-HLA-mismatched related donor (mMRD) or unrelated donor (mMUD), if not mismatched in more than one single HLA allele (bullit) Karnofsky-Index >= 80 % (bullit) No uncontrolled

	infectionsAge at least 18 years
Principal exclusion criteria:	(bullit) Severe organ dysfunction defined as: (bullit) Cardiac left ventricular ejection fraction (LVEF) of less than 35% (bullit) diffusing lung capacity (DLCO) of less than 40% (bullit) total lung capacity (TLC) of less than 40% (bullit) forced expiratory volume (FEV1) of less than 40% (bullit) total bilirubin >3mg/dl (bullit) creatinine-clearance of less than 40 ml/min (bullit) pregnancy or breast feeding (bullit) participation in other experimental drug trials (bullit) Known intolerance to cyclophosphamide (bullit) Presence of hemorrhagic cystitis or urinary tract obstruction (bullit) Presence of uncontrolled infections (bullit) Failure to use highly-effective contraceptive methods for men and women when sexually active (bullit) Persons with any kind of dependency on the investigator or employed by the sponsor or investigator (bullit) Persons held in an institution by legal or official order
Primary endpoints:	(bullit) Number of patients not requiring any additional immunosuppressive treatment until day 100 after allogeneic transplantation

Trial scope

Scope - diagnosis:	N
Scope - prophylaxis:	Y
Scope - therapy:	N
Scope - safety:	Y
Scope - efficacy:	Y
Scope - pharmacokinetic:	N
Scope - pharmacodynamic:	N
Scope - bioequivalence:	N
Scope - dose response:	N
Scope - pharmacogenetic:	N
Scope - pharmacogenomic:	N
Scope - pharmacoeconomic:	N
Scope - others:	N

Trial phase and type

Trial phase - Phase I:	N
First administration to humans:	N
Bioequivalence study:	N
Other type of study:	N
Trial phase - Phase II:	Y
Trial phase - Phase III:	N
Trial phase - Phase IV:	N

Trial design

Trial design - controlled:	N
Trial design - open:	Not answered
Trial design - randomised:	Not answered
Trial design - single blind:	Not answered
Trial design - double blind:	Not answered
Trial design - parallel group:	Not answered
Trial design - cross over:	Not answered
Trial design - other:	Not answered
Trial design - controlled/comparator other medicinal product:	Not answered
Trial design - controlled/comparator placebo:	Not answered
Trial design - controlled/comparator other:	Not answered
Single site in Member State:	Y
Multiple sites in Member State:	N
Multiple Member States:	N
3rd Countries involved - trial conducted both within and outside EEA:	N
3rd Countries involved - trial conducted completely outside the EEA:	Not answered
Data monitoring committee in this trial:	N
Initial estimate of trial duration in this Member State - years:	1

Initial estimate of trial duration in this Member State - months:	0
Initial estimate of trial duration in this Member State - days:	0

Population of trial subjects

Age span

Less than 18 years:	N
In utero:	Not answered
Preterm newborn infants (gestational age less than 37 weeks):	Not answered
Newborn (0 - 27 days):	Not answered
Infant and toddler (28 days - 23 months):	Not answered
Children (2 - 11 years):	Not answered
Adolescents (12 - 17 years):	Not answered
Adults (18 - 64 years):	Y
Elderly (>= 65 years):	N

Gender

Gender - male:	Y
Gender - female:	Y

Group of trial subjects

Subject - healthy volunteers:	N
Subjects - patients:	Y
Subjects - specific vulnerable populations:	Y
Subjects - women of child-bearing potential not using contraceptives (s. Hinweis auf der Webseite):	Y
Subjects - women of child-bearing potential using contraceptives:	Y
Subjects - pregnant women:	N
Subjects - nursing women:	N
Subjects - emergency situation:	N
Subjects incapable of giving consent personally:	N
Subjects - other types of subjects:	N

Planned number of trial subjects

Number of subjects in this Member State:	13

Plans for the treatment or care of subjects after the trial

After the end of the observation period of the trial the patients are regularly beeing seen in the transplantation clinic of the University of Cologne. It is our standard of care to provide lifelong medical care for all patients having received an allogeneic stem cell transplantation at the University of Cologne.

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