

# Aerosolised liposomal cyclosporin A (L-CsA) versus placebo in the treatment of bronchiolitis obliterans (BO) in allogeneic haematopoietic stem cell transplant (HSCT) patients

<b>Submission date</b> 03/07/2008	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/07/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/03/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
CLP 12011.202

## Study information

**Scientific Title**

A phase II, randomised, double-blind, placebo controlled, parallel group, dose-finding clinical trial to investigate the efficacy and safety of 10 and 20 mg/day aerosolised liposomal cyclosporin A (L-CsA) versus placebo in the treatment of bronchiolitis obliterans (BO) in allogeneic haematopoietic stem cell transplant (HSCT) patients

### **Acronym**

L-CsA-HSCT

### **Study objectives**

To establish an investigational medicinal product (IMP) dosage with the most favourable risk-benefit ratio for the prevention of bronchiolitis obliterans (BO) in allogeneic haematopoietic stem cell transplant (HSCT) patients.

Please note that as of 31/07/2008 the sponsor details of this trial changed to PARI Pharma GmbH (Germany). The previous sponsor was Chiltern International (Germany).

As of 12/05/2009 this trial is on hold. The anticipated start and end dates have been amended; the initial trial dates were:

Anticipated start date: 01/11/2008

Anticipated end date: 01/01/2011

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval pending as of 12/05/2009.

### **Study design**

A phase II, multicentre, randomised, double-blind, placebo-controlled, parallel group, dose-finding clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Bronchiolitis obliterans

### **Interventions**

This trial was stopped as of 31/03/2010.

Subjects will be randomised (1:1:1) to one of three treatment arms:

1. 1 x 10 mg/day L-CsA and 1 x placebo/day
2. 2 x 10 mg/day L-CsA
3. 2 x placebo

Subjects will be stratified according to several baseline risk factors, e.g. myeloablative versus non-myeloablative regimen. Treatment duration will be 12 weeks with a 36 week follow-up period. After successful completion of the study, the patient may enter the follow-up clinical trial (ref: 12011.203) after fulfilling in/exclusion criteria.

## **Intervention Type**

Drug

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Liposomal cyclosporin A (L-CsA)

## **Primary outcome(s)**

To establish an IMP dosage with the most favourable risk-benefit ratio for the prevention of BO in HSCT patients.

## **Key secondary outcome(s)**

1. To compare efficacy and safety data from two different L-CsA doses versus placebo
2. To evaluate investigational medicinal product (IMP) pharmacokinetic (PK) data in bronchoalveolar lavage (BAL) and in whole blood samples

## **Completion date**

01/12/2012

## **Reason abandoned (if study stopped)**

Lack of funding/sponsorship

# **Eligibility**

## **Key inclusion criteria**

1. Signed informed consent provided prior to any screening procedure
2. Male or female, 12 years or older
3. Capable of self-administering medications
4. Capable of understanding the purpose and risk of the study
5. Received an allogeneic haematopoietic stem cell transplantation
6. Has a diagnosis of bronchiolitis obliterans of grade 1, 2 or 3 based on forced expiratory volume in one second (FEV1) values according to protocol within one week prior to first investigational medicinal product administration (IMP)
7. Obtained a FEV1 value immediately before HSCT
8. Received within one week prior to first IMP administration the following immunosuppressive treatment and dosages for graft-versus-host-disease (GVHD) including bronchiolitis obliterans:
  - 8.1. Tacrolimus 0.1 to 0.2 mg/kg/day adjusted to a target trough serum level (C0) of 5 to 15 µg/L
  - 8.2. Prednisone 1 to 1.5 mg/kg/day for 2 to 6 weeks
9. Female patients with child bearing potential must have a negative serum pregnancy test within 3 days prior to screening. Both women and men must agree to use a medically-acceptable method of contraception throughout the treatment period and for 3 months after discontinuation of treatment. Acceptable methods of contraception include intra-uterine device

(IUD), oral contraceptive, subdermal implant and double barrier (condom with a contraceptive sponge or contraceptive suppository)

10. Estimated life expectancy greater than 6 months

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria**

1. Has an active invasive bacterial, viral or fungal infection within one week prior to first IMP administration
2. Received systemic maintenance immunosuppressive therapy for GVHD other than listed in the inclusion criteria within one week prior to first IMP administration
3. Received any systemic or topical cyclosporin within one week prior to first IMP administration and/or during the clinical trial
4. Received mechanical ventilation
5. Pregnant or breast feeding woman
6. Has known hypersensitivity to cyclosporin A
7. Has a serum creatinine value of more than 3 mg/dL
8. Unlikely to comply with visits, inhalation procedures or spirometric measurements scheduled in the protocol
9. Receipt of an investigational drug as part of a clinical trial within four weeks prior to first administration of IMP
10. Any co-existing medical condition that in the investigators judgement will substantially increase the risk associated with the subject's participation in the study
11. Psychiatric disorders or altered mental status precluding understanding of the informed consent process and/or completion of the necessary procedures
12. Has been previously enrolled in this study

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

01/12/2012

**Locations**

**Countries of recruitment**

United Kingdom

Austria

Belgium

Denmark

France

Germany

Switzerland

**Study participating centre**

**Clinical Trial Manager**

Munich

Germany

81369

## Sponsor information

**Organisation**

PARI Pharma GmbH (Germany)

**ROR**

<https://ror.org/011pcrd91>

## Funder(s)

**Funder type**

Industry

**Funder Name**

PARI Pharma GmbH (Germany)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration