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

Submission date 03/07/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 10/07/2008	**Overall study status** Stopped	
Last Edited 31/03/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 established 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/03/2010

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-administrating 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

Age group
Other

Sex
Both

Target number of participants
60

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
Austria

Belgium

Denmark

France

Germany

Switzerland

United Kingdom

Study participating centre
Clinical Trial Manager
Munich
Germany
81369

Sponsor information

Organisation
PARI Pharma GmbH (Germany)

Sponsor details
Steinerstrasse 15A
Munich
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81369

Sponsor type
Industry

Website
http://www.paripharma.com

ROR
https://ror.org/011pcrd91

Funder(s)

Funder type
Industry

Funder Name
PARI Pharma GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration