ISRCTN65243779 https://doi.org/10.1186/ISRCTN65243779

A phase IIa, open label study of visilizumab for the treatment of perianal fistulas in patients with Crohn's disease

Submission date 08/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/02/2006	**Overall study status** Completed	
Last Edited 31/01/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Hommes

Contact details
Academic Medical Center
Department of Gastroenterology
Room C2-330
Melbergdreef 9
Amsterdam
Netherlands
1105AZ
-
d.w.hommes@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00267709

Secondary identifying numbers
291-411

Study information

Scientific Title
A phase IIa, open label study of visilizumab for the treatment of perianal fistulas in patients with Crohn's disease

Study objectives
To evaluate the clinical activity of two consecutive daily doses of 10 µg/kg visilizumab administered intravenously to patients with draining perianal fistulas associated with Crohn's disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethics Committee on the 3rd February 2005 (ref: 04 /318)

Study design
Treatment, non-randomised, open labelled, uncontrolled, single group assignment, efficacy study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Crohn's disease

Interventions
Two consecutive daily doses of 10 µg/kg of visilizumab administered intravenously.

1. Taking of blood samples
2. Flexible sigmoidoscopy and biopsy
3. Magnetic resonance imaging (MRI) of fistulas

Intervention Type

Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Visilizumab

Primary outcome measure
To evaluate the clinical activity of two consecutive daily doses of 10 µg/kg visilizumab administered intravenously to patients with draining perianal fistulas associated with Crohn's disease

Secondary outcome measures
1. To evaluate the pharmacokinetics of two consecutive doses of 10 µg/kg visilizumab administered intravenously in this patient population
2. To determine the risk-benefit relationship of visilizumab in this patient population
3. To assess immunogenicity of visulizumab in this patient population
4. To evaluate the safety, clinical activity, pharmacokinetics and immunogenicity of retreatment (if warranted) of two consecutive daily doses of 10 µg/kg visilizumab in patients with perianal fistulas associated with Crohn's disease

Overall study start date
01/10/2004

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Male or female, 18 to 70 years of age
2. A diagnosis of Crohns disease and at least one documented external, draining, perianal fistula
3. Patients with reproductive potential who agree to use double-barrier methods of contraception during the study and for three months after receiving the study drug
4. Women of childbearing potential who have a negative serum pregnancy test at baseline screening
5. Patients who have been tested negative for Clostridium difficile within three weeks prior to treatment with the study drug
6. Patients who are capable of understanding the purpose and risks of the study and who provide signed and dated informed consent and an authorisation to use protected health information (US sites only)
7. Patients who have Epstein-Barr virus (EBV) deoxyribonucleic acid (DNA) titres up to 30,000 copies/ml

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. History of lymphoproliferative disorder or a prior malignancy within five years or current malignancies (excluding non-melanoma skin cancers or in situ carcinoma of the cervix that had been adequately treated)
2. Pregnant women or nursing mothers
3. Any of the following haematological abnormalities: white blood cells (WBC) less than 2500 /mm^3, platelets less than 150,000/mm^3, haemoglobin less than 10 g/dl
4. Serologic evidence of infection with human immunodeficiency virus (HIV) or hepatitis B or C virus (HBV or HCV)
5. Presence of obstructive symptoms, confirmed by endoscopy showing an impassable stricture or computed tomography (CT) or barium studies showing stricture with prestenotic bowel dilation, within six months prior to receiving study drug
6. Likely to require surgery in the next six months, such as those with clinically apparent abscesses or severely symptomatic stenoses (patients with fistula abscesses and/or setons at screening may be eligible for study entry if abscesses can be drained before patients receive study drug)
7. Serious infections, particularly those of viral etiology, e.g. known as active cytomegalovirus (CMV) colitis, and who have a history of opportunistic infections with the past year
8. Active infections that require antibiotic therapy (not to include use of antibiotics to manage Crohns disease)
9. Serious infections that require intravenous (IV) antibiotic therapy or hospitalisation within eight weeks prior to receiving study drug
10. Started, or have had a change of sulfasalazine; 5-aminosalicylic acid (5-ASA) or antibiotics, probiotics, or topical therapies for Crohns disease within two weeks prior to receiving the study drug
11. Had an increased dose of corticosteroid medication within two weeks prior to receiving the study drug, is receiving intravenous (IV) steroids, or, is receiving a daily dose of greater than 40 mg prednisone, greater than 9 mg budesonide or equivalent
12. Received a live vaccine within six weeks prior to receiving study drug (patients may not receive a live vaccine during treatment or for 12 weeks after treatment with the study drug)
13. Received any monoclonal antibodies (including infliximab) or investigational agents or biologics within three months prior to receiving the study drug
14. Received cyclosporine or tacrolimus (FK506) within four weeks of receiving the study drug
15. Had a dose change of, or discontinued from, 6-mercaptopurine, azathioprine or methatrexate within four weeks prior to receiving the study drug
16. Significant organ dysfunction, including cardiac, renal, liver, central nervous system (CNS), pulmonary, vascular, non-Crohns disease related gastrointestinal, endocrine or metabolic (e.g. creatinine greater than 1.6 mg/dl, alanine aminotranferease [ALT] and aspartate aminotransferase [AST] greater than twice the upper limit of normal [ULN], alkaline phosphatase

greater than 1.5 x ULN, history of myocardial infarction, congestive heart failure or arrhythmias within six months prior to study entry)
17. History of proliferative disorder
18. History of tuberculosis (TB) or other mycobacterial infection, or chest X-ray positive for previous TB infection
19. History of thrombophlebitis or pulmonary embolus
20. Histories of immune deficiency or autoimmune disorders other than Crohns disease (not including joint, skin, hepatic, and occular inflammatory conditions that may be components of Crohns disease)
21. History of seizure with subtherapeutic blood levels of anticonvulsive medication (documented) within one week before study enrolment

Date of first enrolment
01/10/2004

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Austria

Belgium

Germany

Netherlands

United States of America

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1105AZ

Sponsor information

Organisation
PDL BioPharma Inc. (USA)

Sponsor details
34801 Campus Drive
Fremont
United States of America

94587
-
mdyer@pdl.com

Sponsor type
Industry

Website
http://www.pdl.com/

ROR
https://ror.org/03ya6pd97

Funder(s)

Funder type
Industry

Funder Name
PDL BioPharma Inc. (USA)

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