

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
Registration date 20/02/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 31/01/2019	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

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

ClinicalTrials.gov (NCT)

NCT00267709

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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 visilizumab 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

Completion date

31/08/2007

Eligibility**Key inclusion criteria**

1. Male or female, 18 to 70 years of age
2. A diagnosis of Crohn's 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

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 /mm³, platelets less than 150,000/mm³, 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 aminotransferase [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 ocular 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)

ROR

<https://ror.org/03ya6pd97>

Funder(s)

Funder type

Industry

Funder Name

PDL BioPharma Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration