

A Phase IIa, Open-Labelled Study of Visilizumab in Patients with Moderate to Severe Inflammatory, Non-Stricturing, Non-Penetrating Forms of 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 08/02/2019	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00267722

Protocol serial number

Study information

Scientific Title

A Phase IIa, Open-Labelled Study of Visilizumab in Patients with Moderate to Severe Inflammatory, Non-Stricturing, Non-Penetrating Forms of Crohn's Disease

Study objectives

To evaluate the clinical activity of two consecutive daily doses of 10 mcg/kg of visilizumab administered intravenously to patients with moderate to severe inflammatory, non-stricturing, non-penetrating forms of Crohn's disease

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medical Ethics Committee on 03/02/2005, (ref: 04/325)

Study design

Treatment, non-randomized, open label, uncontrolled, single group assignment, efficacy study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Crohn's disease

Interventions

Two consecutive daily doses of 10 mcg/kg of visilizumab administered intravenously. Taking of blood samples, endoscopy and biopsies.

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 mcg/kg of visilizumab administered intravenously to patients with moderate to severe inflammatory, non-stricturing, non-penetrating forms of Crohn's disease

Key secondary outcome(s))

1. To evaluate the pharmacokinetics of two consecutive daily doses of 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, tolerability, clinical activity, pharmacokinetics and immunogenicity of retreatment (if warranted) of two consecutive daily doses of 10 mcg/kg visilizumab in patients with moderate-to-severe inflammatory, non-stricturing, non-penetrating forms of 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 moderate-to-severe inflammatory, non-stricturing, non-penetrating Crohns disease, defined as Crohns Disease Activity Index (CDAI) ≥ 250 , C-Reactive Protein (CRP) $\geq$ Upper Limit of Normal (ULN) and endoscopic evidence of moderate-to-severe active inflammatory disease
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 negative serum pregnancy test
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 authorization to use protected health information (US sites only)
7. Patients who have Epstein-Barr virus (EBV) Deoxyribonucleic Acid (DNA) titers up to 30,000 copies/ml

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 has been adequately treated)

2. Pregnant women or nursing mothers
3. Any of the following hematologic abnormalities: White Blood Cell (WBC) $<2500 /\text{mm}^3$, platelets $<150,000 /\text{mm}^3$, hemoglobin $<10 \text{ g/dl}$
4. Serologic evidence of infection with Human Immunodeficiency Virus (HIV) or Hepatitis B or C virus (HBV, 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 the study drug
6. Serious infections, particularly those of viral etiology e.g. known active cytomegalovirus (CMV) colitis, and patients who have had a history of opportunistic infections within the past year
7. Active infections that require antibiotic therapy (not to include use of antibiotics to control Crohns disease)
8. Started, or have a dose 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
9. Serious infections that required intravenous (IV) antibiotic therapy or hospitalization within eight weeks prior to receiving the study drug
10. Had an increased dose in corticosteroid medication two weeks prior to receiving the study drug, is receiving IV steroids, or, is receiving a daily dose of $>40 \text{ mg}$ prednisone, $>9 \text{ mg}$ budesonide, or equivalent
11. Received a live vaccine within six weeks prior to receiving the study drug (patients may not receive a live vaccine during treatment or for 12 weeks after treatment with the study drug)
12. Received any monoclonal antibodies (including infliximab) or investigational agents or biologics within three months prior to receiving the study drug
13. Received cyclosporine or tacrolimus (FK506) within four weeks of receiving the study drug
14. Had a dose change of, or discontinued from, 6-mercaptopurine, azathioprine, or methotrexate within four weeks prior to receiving the study drug
15. Significant organ dysfunction, including cardiac, renal, liver, Central Nervous System (CNS), pulmonary, vascular, non-Crohn's disease-related gastrointestinal, endocrine, or metabolic (e.g. creatinine $>1.6 \text{ mg/dl}$, alanineamino transferase [ALT] or aminotransferase [AST] $>$ twice the Upper Limit of Normal [ULN], alkaline phosphatase $>1.5 \times \text{ULN}$, history of myocardial infarction, congestive heart failure, or arrhythmias within six months prior to receiving the study drug)
16. Likely to require surgery in the next six months, such as those with clinically apparent abscesses or severely symptomatic stenoses
17. History of lymphoproliferative 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 more typically associated with 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

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

Protein Design Labs Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	cytokine release syndrome results				

[Results article](#)

01/04/2009 08/02/2019 Yes No