An Observational Follow-up Study for Subjects Receiving Salvage Therapy After Previous Treatment in a Visilizumab Study for Intravenous Steroid-Refractory Ulcerative Colitis

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Primary: To assess the effects of visilizumab on the safety of subsequent salvage therapies in subjects who experienced disease progression in a previous visilizumab study and subsequently received salvage therapy (see Definitions).Subjects will be...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30550

Source
ToetsingOnline

Brief title
Salvage Therapy After Previous Treatment in a Visilizumab Study

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym
Chronic colon infection, Ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: PDL Biopharma Inc.
Source(s) of monetary or material Support: PDL Biopharma Inc.

Intervention

Keyword: Observational Follow-up Salvage Visilizumab

Outcome measures

Primary outcome

The incidence of medically important events including infections (opportunistic infections and those requiring hospitalization or parenteral therapies), malignancies, lymphoproliferative disorders, pericolectomy complications (up to 60 days postcolectomy), and other surgeries, after the initiation of salvage therapy.

Secondary outcome

Assessment of the following parameters:

Health-related quality of life

*Inflammatory bowel disease questionnaire (IBDQ) total score on Day 45 and the change from baseline (start of salvage therapy) in IBDQ score.

*European quality of life questionnaire (EQ-5D) total score on Day 45 and the change from baseline (start of salvage therapy) in EQ-5D score.

Pharmacoeconomic outcomes

*Resource utilization, as measured by the frequency of hospitalizations, emergency room visits, physician office visits, and surgical and other procedures from the initiation of first salvage therapy to Day 45.

*Work productivity, as measured by the number of days missed from work and

number of reduced activity days from the initiation of first salvage therapy to Day 45.

Efficacy (in subjects who have not had a colectomy)

*Symptomatic response at Days 15 and 45 after start of salvage medication (Modified Truelove & Witts Severity Index [MTWSI] * 9 with * 3-point or 30% reduction).

*Symptomatic remission at Days 15 and 45 after start of salvage medication (MTWSI * 3).

*Durable clinical response at 6 and 12 months after start of salvage medication, as defined by lack of disease progression. Disease progression is defined as a need for a different salvage therapy.

*Time to disease progression after start of salvage medications.

*Colectomy-free at 6 and 12 months after start of salvage medications.

*Time to colectomy after start of salvage medications.

*Prednisone dose (mg/day) at Day 45.

Study description

Background summary

To monitor patients who have participated in previous visilizumab studies and to check their Health-related quality of life.

Study objective

Primary: To assess the effects of visilizumab on the safety of subsequent salvage therapies in subjects who experienced disease progression in a previous visilizumab study and subsequently received salvage therapy (see Definitions). Subjects will be grouped for exploratory analysis in this study based mainly on covariates of interest, such as the study drug they received and their outcomes

in the previous studies. In particular, the following groups will be considered: 1) early visilizumab failures, ie, subjects who did not respond to treatment with visilizumab within 90 days after receipt of study drug, 2) early placebo failures, ie, subjects who did not have a response within 90 days after receipt of placebo, and 3) late treatment failures, ie, subjects who had disease relapse 90 or more days after receipt of visilizumab or placebo. Subjects in the late treatment failure group will also be analyzed as two subgroups (late visilizumab failures and late placebo failures) if appropriate. The rates of medically important events will be summarized for each subject group as appropriate.
Secondary: To assess the health-related quality of life and pharmacoeconomic outcomes of colectomy and other salvage therapies, and the response to salvage medications in subjects who received salvage therapy.

Study design

Observational follow-up study to monitor safety and efficacy in subjects with IVSR-UC who were previously enrolled in a visilizumab study and who experienced disease progression, ie, required salvage therapy (colectomy or immunosuppressive or other experimental medications; see Definitions). While enrolled in this study, subjects may be treated with any salvage therapy including colectomy; immunosuppressive or immunomodulatory medications; biologic or cytotoxic drugs; leukocyte filtration devices; bone marrow or stem cell transplantation; etc. They also may be enrolled concurrently in their previous visilizumab study to complete, per (the previous) protocol, safety follow-ups up to Day 90, followed by quarterly follow-ups up to Month 12 for medically important infections, malignancies, lymphoproliferative disorders, and surgery.

Study burden and risks

Generally, 3 years from the time of enrollment in this protocol. However, if a subject receives a colectomy, the follow-up period is 1 year from the time of surgery, regardless of when the colectomy occurs within the 3-year follow up. Subjects also may be enrolled concurrently in their prior study in order to complete, per the previous protocol, a 90-day safety follow up and a 1-year follow up for medically significant infections, malignancies, lymphoproliferative disorders, and surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Previous participation in a visilizumab study of IVSR-UC.
-Disease progression while enrolled in a previous visilizumab study, and subsequent treatment with salvage therapy (see Definitions).

Exclusion criteria

Unable to understand the purpose and risks of the study, or unwilling or unable to provide a signed and dated informed consent.
For U.S. sites, unwilling or unable to provide authorization to use protected health information.

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-08-2006
Enrollment:	27
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Nuvion
Generic name:	Visilizumab

Ethics review

Approved WMO Date:	25-08-2006
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-10-2006
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2005-004105-28-NL
ClinicalTrials.gov	NCT00355901
CCMO	NL13689.018.06