A double-blind, randomised, placebo-controlled multicenter study to asses the safety and efficacy of AST-120 in mild to moderately active Crohn's patients with fistulas.

Published: 11-09-2006
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The primary efficacy endpoint is treatment success in the therapy for mild to moderate Crohn*s disease with fisultas defined by: - A reduction of at least 50% in the number of draining fistulas at both week 4 and week 8

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON30808

Source
ToetsingOnline

Brief title
Study to asses the safety and efficacy of AST-120

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflamattory bowel dissease

Research involving
Human

Sponsors and support

Primary sponsor: Ocera Therapeutics, Inc.
Source(s) of monetary or material Support: Bedrijf: Ocera Therapeutics;Inc. 12651 High Bluff Drive;Suite 230;San Diego;CA 92130;USA

Intervention

Keyword: AST-120, Efficacy, Evaluation, Safety

Outcome measures

Primary outcome

The primary efficacy endpoint is treatment success in the therapy for mild to moderate Crohn*s disease with fisultas defined by: - A reduction of at least 50% in the number of draining fistulas at both week 4 and week 8

Secondary outcome

- 100% non-draining fistulas at both week 4 and week 8 (complete response)- Absolute numbers of draining fistulas at week 4 and week 8- Change in CDAI scores from baseline at week 4 and week 8- Change in PDAI scores from baseline at week 4 and week 8- Time to relapse from success at week 8- Average frequency of liquid bowel movements during the first 8 weeks- Change in CRP levels from baseline at week 4 and week 8- Treatment failure due to the need for a change in drug therapy needed to treat mild to moderately active Crohn*s disease at week 4 and week 8

Study description

Background summary

Phase 3, multicenter, prospective, double-blind, randomized, placebo-controlled, parallel group, two armed study where patients are

randomized to receive either AST-120 or placebo for 8 weeks. The proportion of patients in each treatment arm that responds to study drug treatment will be compared. Patients who fail the first full course (8 weeks) of randomized treatment will have the option to receive the alternate blinded treatment for one treatment course. Patients who do not respond to the alternate treatment or continue to fail after 4 weeks will be discontinued from the study. Note: Patients who do not show a reduction of at least 50% of draining fistulas until week 8 will be considered late responders, and will not be eligible to receive the alternate blinded treatment

Study objective

The primary efficacy endpoint is treatment success in the therapy for mild to moderate Crohn*s disease with fisultas defined by: - A reduction of at least 50% in the number of draining fistulas at both week 4 and week 8

Study design

Phase 3, multicenter, prospective, double-blind, randomized, placebo-controlled, parallel group, two armed study where patients are randomized to receive either AST-120 or placebo for 8 weeks. The proportion of patients in each treatment arm that responds to study drug treatment will be compared. Patients who fail the first full course (8 weeks) of randomized treatment will have the option to receive the alternate blinded treatment for one treatment course. Patients who do not respond to the alternate treatment or continue to fail after 4 weeks will be discontinued from the study. Note: Patients who do not show a reduction of at least 50% of draining fistulas until week 8 will be considered late responders, and will not be eligible to receive the alternate blinded treatment

Intervention

3 times per day 2g AST-120 or placebo

Study burden and risks

Known side effects of AST-120 involve gastrointestinal symptoms. Constipation was the most common adverse event overall. Abdominal pain, diarrhoea, nausea/vomiting, rectal bleeding and feeling of a full stomach, occurred in 1-2% of the persons treated with AST-120 in previous studies.

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

-18 to 70 years of age
-Body Weight: (>=40 kg)
-Documented diagnosis of Crohn*s disease, including patients with documented diagnosis of ileitis, colitis, or ileocolitis
-Presence of at least one draining perianal fistula. Patients with enterocutaneous fistula can be included if they have >= 1 draining perianal fistula. Women with rectovaginal fistulas are included if they have >= 1 draining perianal fistula.
-Crohn*s Disease Activity Index (CDAI) score < 400
-Platelet count (thrombocytes) >= 100,000/µL
-Able and willing to comply with all protocol procedures

Exclusion criteria

Patients previously treated with infliximab for fistulas caused by Crohn*s disease and who did not respond to infliximab therapyInfliximab therapy within 3 months prior to enrollment in the

studyPresence of symptomatic strictures or suggestion of significant clinical obstructionPatients with setons; unless setons are removed within 48 hours prior to study entryPresence of entero-entero, recto-vesicular, entero-vesicular fistulas§ The patient is unable to stay on a stable dose of concomitant Crohn*s disease medication(s) for at least 10 weeks in the opinion of the investigator§ Currently symptomatic untreated diarrhea due to conditions other than mild to moderately active Crohn*s disease (e.g. bacterial or parasitic gastroenteritis, bile salt diarrhea, etc.)§ Severe diarrhea defined by > 10 liquid bowel movements per day§ Other local manifestations of mild to moderately active Crohn*s disease such as abscesses, or other disease manifestations for which surgery might be indicated, or which might preclude utilization of a CDAI to assess response to therapy (e.g. short bowel syndrome)§ Receiving Total Parenteral Nutrition (TPN) as the sole source of nutrition within 3 weeks of Screen§ Hemoglobin < 8.5 g/dL (females) or hemoglobin < 10 g/dL (males) at Screen§ Women who are pregnant, breast feeding, or planning to become pregnant during the study§ Diagnosis of a psychiatric disorder within the past 2 years and not on a stable dose of medication for at least 6 months § Other major physical or major psychiatric illness within the last 6 months that in the opinion of the investigator would affect the patient*s ability to complete the trial§ Uncontrolled systemic disease § Patients undergoing chemotherapy for the treatment of cancer

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2007
Enrollment:	9
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	AST-120
Generic name:	AST-120

Ethics review

Approved WMO Date:	11-09-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-03-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-05-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-07-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-08-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	06-09-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-10-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2005-005363-28-NL
CCMO	NL14133.078.06