A phase IIa, randomised, double-blind, placebo-controlled, parallel-arm, multicenter study to evaluate the efficacy and safety of tralokinumab (CAT-354), a recombinant human monoclonal antibody directed against interleukin-13 (IL-13), as add-on therapy, on clinical response in patients with active, moderate-to-severe, ulcerative colitis

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Primary: assess the effect of tralokinumab compared with placebo in patients with active ulcerative colitis by assessment of clinical response, as defined by the Mayo score, at week 8.Other objectives: assess the change in (partial) Mayo scores...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON37913

Source
ToetsingOnline

Brief title
D2211C00001

Condition

- Gastrointestinal inflammatory conditions

Synonym
UC, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: Opdrachtgever (AstraZeneca)

Intervention

Keyword: efficacy, safety, tralokinumab, ulcerative colitis

Outcome measures

Primary outcome

The primary study parameter is clinical response, defined as a decrease in Mayo score from baseline of at least 3 points and at least 30% with an accompanying decrease in the sub score for rectal bleeding of at least 1 point or absolute sub score for rectal bleeding of 0 or 1.

Secondary outcome

-Change from baseline in Mayo score

-Mucosal healing, defined as an improvement of the endoscopy subscore (from the Mayo score) from 3 or 2 to 0 or 1 point, or from 1 to 0 points

-Change from baseline in partial Mayo score

-Clinical remission, defined as Mayo score of 2 or lower with no individual subscore exceeding 1 point

-Histologic disease activity: modified Riley score

-Markers of disease activity and intestinal leakiness in serum and faeces: CRP

and albumin (in serum), calprotectin (in faeces)

-Immunogenicity: incidence of anti-drug antibodies (ADA) to tralokinumab in

serum

-Plasma pharmacokinetics (PK) parameters

-Safety measurements

Study description

Background summary

Moderate to severe ulcerative colitis represents an area of unmet medical need as currently available therapies frequently fail to prevent significant morbidity and mortality. Long-term studies indicate that approximately 50% of ulcerative colitis patients relapse in any given year, what has a considerable impact on patients' quality of life and their use of healthcare resources. Tralokinumab has been shown to be a potentially safe and efficacious therapy for moderate to severe asthma. Tralokinumab targets IL-13 and IL-13 has been implicated in the pathogenesis of ulcerative colitis. This study will evaluate if tralokinumab has potential as a novel therapy for ulcerative colitis when added to standard therapies.

Study objective

Primary: assess the effect of tralokinumab compared with placebo in patients with active ulcerative colitis by assessment of clinical response, as defined by the Mayo score, at week 8.

Other objectives: assess the change in (partial) Mayo scores throughout the study, assess mucosal healing at week 8, assess markers of disease activity and intestinal leakiness in serum and faeces, assess pharmacokinetics and immunogenicity of tralokinumab, evaluate safety and tolerability.

Study design

Randomised, double-blind, placebo controlled, phase IIa study to compare tralokinumab (300 mg sc) with placebo.
The study lasts 25 weeks for every patient and consists of 11 visits: a screenings visit, 7 treatment visits every other week and 3 follow-up visits

every 4 weeks.

About 110 patients will participate in the study in about 40 centres in 8 European countries. In the Netherlands, about 12 patients will be enrolled in about 4 centres.
First subject in is planned for 15 February 2012 and last subject last visit is planned for 4 February 2013.

Intervention

Tralokinumab (CAT-354, a human anti interleukin 13 (IL-13) monoclonal antibody) 300 mg or placebo will be administered as 2 sc 150 mg injections every 2 weeks during a 12 week period.

Tralokinumab or placebo is given as add-on therapy to the standard treatment of ulcerative colitis.

Study burden and risks

Tralokinumab has been studied in a limited number of people and therefore it's side effects may not be fully known at this time. The side effects reported in 6 clinical studies with tralokinumab in asthma patients were:
-asthma
-signs of infection in the urine
-low blood levels of cells that fight infection
-cold-like symptoms (sore throat, coagh, headache)
-feeling tired
-diarrhoea
-tootache
-pain on injection site
-acute hypersensitivity reaction
Patients can experience discomfort during the assessments of this study (for example during taking blood samples and during endoscopy and biopsy collections)

Contacts

Public
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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Diagnosed ulcerative colitis at least 90 days prior randomisation.;2. Men or women age18 - 75 years. ;3. Non-hospitalized patients with moderate-severe ulcerative colitis treated with stable background UC therapy (e.g. containing 5-aminosalisylates, and/or low dose of glucocorticosteroids, and/or purine analogue) prior to randomization;4. Females of childbearing potential who are sexually active with a nonsterilized male partner must use highly effective contraception from Day1. ;5. Nonsterilized males or sterilized males who are <= 1 year post-vasectomy who are sexually active with a female partner of childbearing potential must use a highly effective method of contraception.

Exclusion criteria

1. Pregnant or breastfeeding women. ;2. History of colostomy.;3. Current diagnosis of indeterminate colitis, Crohn*s disease, ischemic colitis, fulminant colitis and/or toxic megacolon and patients with ulcerative colitis limited to the rectum (ulcerative proctitis). ;4. Hepatitis B, C or HIV.;5. History of cancer.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	15-02-2012
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	nog niet bekend
Generic name:	tralokinumab

Ethics review

Approved WMO Date:	22-12-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-01-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-02-2012
Application type:	Amendment

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-03-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-03-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-04-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-06-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-07-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-08-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2011-004812-40-NL
CCMO	NL38894.028.11