A PHASE II, RANDOMIZED, PARALLEL-GROUP, DOUBLE-BLIND, DOUBLE-DUMMY, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF UTTR1147A COMPARED WITH PLACEBO AND COMPARED WITH VEDOLIZUMAB IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

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This study will evaluate the safety, efficacy, and pharmacokinetics of UTTR1147A compared with placebo and compared with vedolizumab in patients with moderate to severe ulcerative colitis (UC).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal ulceration and perforation
Study type	Interventional

Summary

ID

NL-OMON46667

Source
ToetsingOnline

Brief title
Roche GA39925

Condition

- Gastrointestinal ulceration and perforation

Synonym
Ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Hoffmann-La Roche
Source(s) of monetary or material Support: pharmaceutical company/industry

Intervention

Keyword: ULCERATIVE COLITIS, UTTR1147A, VEDOLIZUMAB

Outcome measures

Primary outcome

To evaluate the efficacy of UTTR1147A compared with placebo and compared with vedolizumab

Secondary outcome

* Evaluate the efficacy of UTTR1147A compared with placebo and compared with vedolizumab

* Evaluate the safety of UTTR1147A compared with placebo and compared with vedolizumab

* Characterization of the pharmacokinetics of UTTR1147A in patients with CU

* Evaluate the potential relationships between exposure to the medicine and the efficacy and safety of the research tool

* Evaluate the potential relationships between selected covariates and exposure to UTTR1147A

* Evaluate the immune response to UTTR1147A

* Evaluate the potential effects of ADAs

* Identify biomarkers that are predictive of the response to UTTR1147A (ie predictive biomarkers), related to progression to a more severe state of the disease (ie prognostic biomarkers), related to susceptibility to the development of adverse events (ie safety biomarkers), that can provide evidence for UTTR1147A activity (ie pharmacodynamic biomarkers) or increase knowledge and understanding of the biology of the disease

Study description

Background summary

Currently there is no available therapy which achieves sustained remission in more than 10%-30% of patients with chronic IBD.
UTTR1147A, an IL-22 fusion protein, is a novel therapeutic agent being developed to promote mucosal healing and achieve sustained clinical remission while potentially allowing reduction or elimination of the immunosuppression associated with current therapies for UC.
The safety profile of UTTR1147A, as demonstrated in the Phase I studies, supports further investigation to compare UTTR1147A with placebo and with vedolizumab in the induction and maintenance of clinical remission for patients who have failed conventional therapy.

Study objective

This study will evaluate the safety, efficacy, and pharmacokinetics of UTTR1147A compared with placebo and compared with vedolizumab in patients with moderate to severe ulcerative colitis (UC).

Study design

This is a Phase II, randomized, parallel-group, double-blind, double-dummy, placebo-controlled, multicenter study to evaluate the efficacy, safety, and pharmacokinetics of UTTR1147A compared with placebo and compared with vedolizumab in the treatment of moderate to severe UC.

Intervention

Part A
During Part A, patients will receive IV infusions of UTTR1147A, UTTR1147A placebo,
vedolizumab, or vedolizumab placebo. At Week 0 only, two IV infusions will be administered.
At Weeks 2, 4, 6, and 8, patients will receive one IV infusion (see treatment regimens outlined
above).

Part B
During Part B, patients will receive IV infusions of UTTR1147A and vedolizumab placebo
(Arms 1A, 2A, and 3A), UTTR1147A placebo and vedolizumab placebo (Arms 1B, 2B, 3B, and
5), or vedolizumab and UTTR1147A placebo (Arm 4) at Weeks 14 and 22.

Study burden and risks

You may get side effects from the medicines or procedures used in this study. Side effects may vary from mild to very severe and may vary from person to person. Everyone who participates in the study is closely monitored for any side effects. Genentech, the research doctor and other doctors do not know all the side effects that can occur. Your research physician can give you medication to help reduce these side effects and you may need to temporarily or permanently stop using UTTR1147A or vedolizumab. Many side effects disappear quickly after you stop what causes them. In some cases, side effects can be serious, persist for a long time or never disappear. In rare cases there is also a risk of death. You should immediately talk with your research physician about any side effects you get while you are taking part in the study. You should also tell your research physician if you have started new medication, including medication that is available free of prescription and alternative medicines.

Contacts

Public
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CH

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

- Age 18-80 years
- Diagnosis of Ulcerative Colitis (UC)
- Moderate to severely active UC, defined by the Mayo Clinic Score
- Inadequate response, loss of response, or intolerance to prior immunosuppressant treatment and and/or corticosteroid treatment
- Use of highly effective contraception as defined by the protocol

Exclusion criteria

- History of psoriasis or psoriatic arthritis; any other inflammatory skin disorders requiring oral corticosteroids, immunosuppressants, or biological therapy within the previous year and primary sclerosing cholangitis
- History of cancer as defined by the protocol
- Significant uncontrolled comorbidity, such as cardiac, pulmonary, renal, hepatic, endocrine, or GI disorders (excluding UC)
- Prior extensive colonic resection, subtotal or total colectomy, or proctocolectomy, or planned surgery for UC
- Diagnosis of indeterminate colitis or granulomatous (Crohn's) colitis and toxic megacolon within 12 months prior to screening

- Suspicion of ischemic colitis, radiation colitis, or microscopic colitis
- Current fistula or history of fistula, current pericolonic abscess and Stricture (stenosis) of the colon
- History or current evidence of unresectable colonic mucosal dysplasia and high-grade colonic mucosal dysplasia
- Prior treatment with vedolizumab, etrolizumab, natalizumab, efalizumab, or any other anti-integrin agents and rituximab
- Use of prohibited therapies as defined by the protocol prior to randomization
- Evidence or treatment of infections or history of infections as defined by the protocol

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
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Entyvio
Generic name:	Vedolizumab
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	UTTR1147A
Generic name:	Human Interleukin IL-22 fusion protein

Ethics review

Approved WMO Date:	24-04-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	31-07-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-08-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-10-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-07-2019
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	EUCTR2017-002350-36-NL
CCMO	NL64245.028.18