IM011-127 A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Efficacy, and Biomarker Response of BMS-986165 in Subjects with Moderate to Severe Ulcerative Colitis

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Study IM011-127 is a Phase 2 randomized, double-blind, placebo-controlled, multicenter clinical study designed to assess the safety and tolerability, efficacy and biomarker response of BMS-986165 12 mg BID in subjects with moderate to severe...

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal ulceration and perforation
Study type	Interventional

Summary

ID

NL-OMON51968

Source
ToetsingOnline

Brief title
IM011-127

Condition

- Gastrointestinal ulceration and perforation

Synonym
inflammation of the large intestine, ulcers of the colon

Research involving

Human

Sponsors and support

Primary sponsor: Bristol-Myers Squibb
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: immune-mediated, targetted therapy, TYK 2, Ulcerative colitis

Outcome measures

Primary outcome

The primary objective of the study is to estimate the efficacy of BMS-986165 at

Week 12

This will measured by the proportion of subjects in clinical response at Week

12

Secondary outcome

Secondary objectives of the study will be as follows:

1. to assess the safety and tolerability of BMS-986165. This will be measured

by the Number and proportion of subjects experiencing Adverse Events (AE),

Serious AEs, AEs leading to discontinuation from the study, and AEs of interest

(AEI) throughout the study

2. to estimate the effect of BMS-986165 on inflammatory biomarkers. This will

be measured by the change in baseline in biomarkers of inflammation over time.

3. To explore the efficacy of BMS-986165 at Week 12. This will be measured by:

i. Proportion of subjects in clinical remission at Week 12

ii. Change from baseline in modified Mayo score at Week 12

iii. Change from baseline in individual subscores of the modified Mayo score at Week 12

iv. Change from baseline in the UC-100 score at Week 12

4. To explore the efficacy of BMS-986165 over time. This will be measured by:

i. Change from baseline in the Stool Frequency (SF) and Rectal Bleeding (RB) subscores at over time

ii. Change from baseline in the sum of the SF and RB subscores over time

iii. Proportion of participants in symptomatic remission over time

iv. Change from baseline in partial Mayo score over time

5. To explore the effect of BMS-986165 on the endoscopic appearance of the

mucosa. This will be measured by:

i. Change from baseline in the UC Endoscopic Index of Severity (UCEIS) score at Week 12

Ii. Proportion of subjects in endoscopic remission at Week 12

Iii. Proportion of subjects in endoscopic improvement at Week 12

Iv. Proportion of subjects with endoscopic response at Week 12

6. To explore the effect of BMS-986165 on the histological appearance of the mucosa. This will be measured by:

i. Change from baseline in the Robarts Histopathology Index (RHI) at Week 12

Ii. Proportion of subjects in histologic improvement by Geboes score

7. To explore the efficacy of BMS-986165 at Week 52. This will be measured by:

i. Proportion of subjects in clinical remission at Week 52

Ii. Proportion of subjects in clinical response at Week 52

Iii. Proportion of subjects in endoscopic remission at Week 52

Iv. Proportion of subjects with endoscopic improvement at Week 52

v. Proportion of subjects with histologic improvement at Week 52.

vi. Proportion of subjects with corticosteroid-free remission at Week 52.

8. To estimate the effect of BMS-986165 on inflammatory biomarkers. This will be measured by a change in baseline in biomarkers of inflammation over time.

9. To explore the effect of BMS-986165 on peripheral blood (PB) immune cells. This will be measured by a change from baseline in PB immune cells over time.

10. To explore the effect of BMS-986165 on mucosal cells. This will be measured by a change from baseline in mucosal cells at week 12.

11. To explore the effect of BMS-986165 on the intestinal microbiome in stool and colon mucosa. This will be measured by a change from baseline in the

intestinal microbiome over time.

12. To explore the effect of BMS-986165 on the metabolome in stool and serum. This will be measured by a change from baseline in metabolome over time.

13. To explore the effect of BMS-986165 on the transcriptome in blood and colon biopsies. This will be measured by a change from baseline in gene expression.

14. To explore the effect of BMS-986165 on the epigenetics in PB immune cells and colon biopsies. This will be measured by a change from baseline in epigenetics.

15. To explore the PK of BMS-986165. This will be measured by comparing concentrations of BMS-986165, BMT-153261, and other metabolites (if applicable) at various timepoints.

16. To explore the effect of BMS-986165 on PROs and quality of life. This will be measured by a change from baseline at various timepoints for the inflammatory bowel disease questionnaire (IBDQ).

17. To explore the effect of BMS-986165 on UC-related hospitalization and surgery. This will be measured by the proportion of subjects with surgery and/or hospitalisation due to UC at various time points.

Study description

Background summary

IM011-127 is a multicentre, phase 2, double-blind study involving patients with moderate to severe Ulcerative Colitis (UC). The study will assess the safety and efficacy of BMS-986165 at two dose levels (6mg and 12mg), compared with placebo. The placebo arm is included in this study design to mitigate bias in the reporting of safety data and patient reported outcomes. Previous research and pharmacology data models show that greater target engagement may be achieved when the dose is increased from 6mg twice daily (BID).

UC is a chronic inflammatory disease of the gastrointestinal tract which has an impact on mortality and quality of life. The management and treatment of the disease has placed a huge demand on various healthcare services. Despite new treatment options which have become available over the last several years, significant challenges remain. Current treatments are often ineffective, only inducing are temporary response. In other cases the treatment regimens can cause toxic side effects. There is still remains a significant need for well-tolerated and effective treatments. For example, studies with tumour necrosis factor inhibitors (TNFi) report that 10% to 30% of subjects do not respond to their first treatment and 23% to 46% of subjects lose their response over time. Therefore, there is still an unmet need for novel, safe, well-tolerated, and orally administered therapies that can effectively treat UC and modify the disease course.

BMS-986165 is a selective Tyrosine Kinase 2 (TyK2) inhibitor. TyK2 is an enzyme involved in various signalling pathways found within the cell known as cytokines: interlukin (IL)-12, IL-23 and Type I interferon (IFN) signalling. The TyK2 enzyme works by speeding up the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific proteins. This process is known as phosphorylation. The phosphorylation of these proteins results in the downstream activation of specific responses for these signalling pathways.

TyK2 is widely expressed. TYk2-dependent signalling pathways and the chemical messengers that they modulate are thought to be involved in the onset and development of various immune-mediated diseases including UC, Crohn's disease (CD), psoriasis, psoriatic arthritis and systemic lupus erythematous (SLE).

Data from this study will be analysed to:
(i) estimate the efficacy of BMS-986165 12 mg twice daily in patients with moderate to severe UC;
(ii) evaluate the safety and tolerability of BMS-986165 in that patient population;
(iii) estimate the effect of BMS-986165 on biomarkers (signalling factors in

the blood) of inflammation;
(iv) explore if biomarkers are associated with a clinical response to BMS-986165 or are predictive of clinical response;
(v) determine if biomarkers should be further studied in the Phase 3 clinical trial program;

Study objective

Study IM011-127 is a Phase 2 randomized, double-blind, placebo-controlled, multicenter clinical study designed to assess the safety and tolerability, efficacy and biomarker response of BMS-986165 12 mg BID in subjects with moderate to severe Ulcerative Colitis. The primary objective is to estimate the effect of BMS-986165 on clinical response at Week 12.

Study design

Study IM011-127 is a multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase 2 clinical trial designed to assess the safety and tolerability, efficacy, and biomarker response of BMS-986165 12 mg twice daily, orally following a 12-week treatment period. An additional 40-week Open Label Extension (OLE) period (to Week 52) is available for eligible subjects.

Approximately 50 patients will participate in the study, with 10 expected to take part from the Netherlands

The study is divided into a screening period, 2 treatment periods and a follow-up period. The first treatment period will be double-blind. The effectiveness of the study treatment will be compared to the effectiveness of a placebo. Patients will be assigned by chance to one of two treatment groups:

• Group 1: BMS-986165 12 mg twice a day, or
• Group 2: Placebo twice a day.

Patients must be randomised within 14 calendar days of the screening endoscopy assessment. Randomisation will be done by an automated sorting process through IVRS (a telephone based computer system). This maintains the integrity of the randomisation itself. To be eligible for randomisation patients must meet the inclusion criteria and must not meet any of the exclusion criteria. Patients will be expected to complete an electronic diary throughout the screening period. The diary will be reviewed by the hospital research team to calculate a Mayo score. This will contribute to the eligibility assessment.

There is an 75% chance the patient will receive BMS-986165 and a 25% chance of receiving placebo. This double-blind treatment period will last up to 12 weeks.

The second treatment period will be open-label. Patients will receive BMS 986165 6 mg twice a day. This open-label extension treatment period will last up to 40 weeks.

After patients have completed the treatment period or for those who permanently discontinue the study drug before the end of the treatment period, they will enter a 4 week post treatment follow-up period.

Intervention

Patients who have completed screening procedures (up to 28 days duration) and met inclusion/exclusion criteria will be randomized on Day 1 of the treatment period.

Patients will be randomized in a 3:1:1 ratio using interactive response technology (IRT) to one of three arms:

Arm A (Treatment arm)
oral BMS-986165 12 mg, twice daily

Arm C (Control arm)
BMS-986165 placebo, twice daily

Patients in all arms will undergo the same study evaluation procedures: assessments of medical and Ulcerative Colitis (UC) disease history, prior medications, concomitant medications and UC medications, tobacco use, baseline Stool Frequency; blood, stool and urine collection for checking safety, pharmacokinetics, and biomarkers, vital signs monitoring, endoscopy with biopsies, ECG, additional efficacy assessments and the physician*s global assessment (PGA); and patient collection of PROs in daily electronic diaries.

After patients complete the first treatment period, they may be eligible to enter the Open-label Extension Period: Subjects who are likely to derive a clinical benefit from ongoing participation in the study following Week 12, as judged by the investigator, are eligible to enter the OLE period and receive the following study treatment:

BMS-986165 6 mg BID

Patients who complete the Week 12 visit and decline to enter the OLE period, those who complete the Week 52 visit, or those who permanently discontinue study drug at any time during the study (Section 7) will enter a 4-week post-treatment follow-up period.

Study burden and risks

Several sources of research suggest that inhibition of TYK 2 signalling by BMS-986165 may be beneficial to patients with active Ulcerative Colitis (UC). Study IM0111-27 is the first study involving patients with moderate to severe UC, receiving BMS-986165 at doses above 6 mg BID PO. The BMS-986165 12 mg BID treatment regimen has not been studied previously in UC patients. Therefore the study has been designed to closely monitor patients safety throughout. Safety monitoring will occur at study sites, by the Sponsor, and also by an external, independent Data Monitoring.

Adverse Events of Interest (AEIs) have been defined, based on the mechanism of action of BMS-986165 and the observed safety profile in the BMS-986165 clinical trial program. The eligibility and randomisation criteria have been clearly defined to ensure that subjects have *failed* at least 1 first-line standard of care medication (ie, had a primary nonresponse, secondary loss of response, or intolerance), have active UC on randomisation, and also to minimize the risk for AEIs such as infections or malignancy, which may be associated with immunomodulator use. Frequent study visits and safety assessments, with monitoring of subject safety by investigators, the Sponsor, and the Data Monitoring Committee are designed to promote the safety of subjects within this study. In addition, the protocol provides clear recommendations on the recognition and management of AEs that have been observed with BMS-986165 12 mg BID in completed Normal Healthy Volunteer studies.

Medical Monitoring by the Sponsor
Patient safety will be monitored in a blinded manner by the Sponsor on a regular basis. The Sponsor will review blinded patient-level data entered in the clinical database as well as aggregated safety data across studies. This approach facilitates close monitoring of individual safety events as well as surveillance for potential safety signals.

Data Monitoring Committee (DMC)
An external, independent DMC will provide oversight on the safety of patients within this study, The DMC will regularly review accumulating data from this study, and advise the Sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

Data summaries and listings will be provided to the DMC to facilitate their safety assessment at regularly scheduled meetings and on an ad-hoc basis if needed. The DMC will also be provided with suspected, unexpected serious adverse reaction (SUSAR) reports relating to BMS-986165 and recommendations from other DMCs supporting the BMS-986165 clinical development program.

Regular DMC safety reviews will include all AEs, SAEs, and AEIs. Based on their review of safety data, the DMC will make recommendations regarding the appropriateness of continuing the study, with or without study modifications, or stopping the study.

In addition to regularly scheduled DMC meetings, ad hoc DMC meetings will occur in the following circumstances:

- Two or more subjects experience an SAE of the same preferred term and that is considered related to the study treatment by the investigator (for example, not explained by intercurrent medical condition or concomitant medication)
- Two or more subjects are discontinued due to the same laboratory abnormality as defined in section 7.1 in the protocol

As part of the trial, patients will be expected to attend multiple clinic visits where they will undergo physical examinations, vital sign measurements, endoscopy, biopsy, ECG, blood, stool and urine tests for safety assessment, pregnancy testing (for females of child bearing potential) and monitoring for adverse events. Blood will also be collected at certain visits for research purposes (Pharmacokinetic and biomarker studies).

Patients will be asked to complete an electronic diary about their stool frequency and any occurrence of rectal bleeding, daily, throughout the screening and treatment periods. They will also be required to complete questionnaires about their ulcerative colitis disease and quality of life and various points throughout the study.

Patients will be required to take tablets twice daily for up to 52 weeks, during the treatment period. The diary and pill bottle will be reviewed by site-staff. Study treatment may be taken without regard to meals. Patients are required to fast for a minimum of 10 hours before the randomization visit (Day 1) and the Week 12 (Day 85) visit, as fasting lipid and glucose blood samples will be obtained at those times.

Women of child-bearing potential must agree to follow instructions for methods of contraception for the duration of treatment with the study medicine.

BMS-986165 could provide clinical benefit and improvements in the outcomes for patients with UC. However, with all experimental drugs and clinical trials, there are known and unknown risks. Study medication and procedure related risks are outlined in the patient information sheet in detail to ensure the patients are fully informed before agreeing to participate.

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

1.) Type of Participant and Target Disease Characteristics

a. A diagnosis of Ulcerative Colitis (UC) at least (>=) 3 months* duration prior to screening and source documents must include (i) an endoscopy report, which shows features consistent with UC, and (ii) a histopathology report showing features consistent with UC.

If an endoscopy report is not available prior to screening, the screening endoscopy can be used to confirm the diagnosis. If a histopathology report is not available prior to screening, endoscopic biopsies can be obtained at the screening endoscopy (with appropriate consent) and sent to a local histopathology laboratory for reporting, to meet the criteria described above prior to randomization.

b. UC disease distribution extending proximal to the rectum (ie, left-sided colitis or pancolitis)

c. Moderately to severely active UC, defined by a modified Mayo score of 5 to 9 points inclusive, which includes all of the following:

i. A stool frequency (SF) subscore of >= 2, and
ii. A rectal bleeding (RB) subscore >= 1, and
iii. An endoscopic (ES) subscore of >= 2

d. Must be up to date with surveillance for dysplasia and screening for colorectal neoplasia, according to local standard of care

2.) Age and Reproductive Status

a. Males and Females, ages 18 (or local age of majority) to 65 years, inclusive, at the time of screening.

b. Women who are not of child-bearing potential are exempt from contraception requirements. Female subjects must have documented proof that they are not of childbearing potential

c. Women of Child Bearing Potential (WOCBP) must have a negative highly sensitive serum or urine pregnancy test.
(minimum sensitivity 25 IU/L or equivalent units of human chorionic gonadotropin) within 24 hours prior to the start of study treatment. If a urine test cannot be confirmed as negative (eg, an ambiguous result), a serum pregnancy test is required. The participant must be excluded from participation if the serum pregnancy result is positive.

d. A female subject is eligible to participate if she is not pregnant or breastfeeding and at least one of the following conditions applies:
(1) Is not a WOCBP
OR
(2) a WOCBP and using a contraceptive method(s) as described in the protocol during the intervention period (at a minimum until after the last dose of study intervention)

e. Males who are sexually active with WOCBP must agree to follow instructions for contraception as desribed in the protocol

f. Azoospermic males are exempt from contraceptive requirements

3.) Prior UC Medication Failure Inclusion Criteria

a. Documentation of an inadequate response, loss of response, or intolerance to a treatment course of 1 or more of the following standard of care medications:

i. Oral 5-aminosalicylic acids (5-ASAs) (eg, mesalamine, sulfasalazine, olsalazine, or balsalazide)

ii. Corticosteroids (eg, prednisone or budesonide MMX)

iii. Immunomodulators (eg, azathioprine [AZA], 6-mercaptopurine [6-MP], or methotrexate [MTX]

iv. Anti-TNF agents (eg, infliximab, adalimumab, or golimumab)

v. Integrin inhibitors (eg, vedolizumab)

vi. Anti-IL-12/IL-23p40 antibodies (eg, ustekinumab): subjects can only be included if they were intolerant to treatment. Inadequate response or loss of response is an exclusion factor.

4.) Washout and Dose Stabilization Inclusion Criteria

a. Must comply with washout periods for prohibited concomitant medications summarized in the protocol

b. Must comply with dose stabilization rules for 5-ASAs, corticosteroids and probiotics (if applicable) prior to randomization, as listed in the protocol

Exclusion criteria

1.) Medical Conditions

a. Women who are pregnant or breastfeeding

2.) Ulcerative Colitis (UC) Exclusion Criteria

a. UC involving the rectum only (UC proctitis).

b. Current diagnosis of Crohn*s disease, indeterminate colitis, ischemic colitis or microscopic.

c. Current or recent (within 12 weeks prior to randomization) evidence of fulminant UC (also known as acute severe UC) or toxic megacolon.
d. Current or recent (within 12 weeks prior to randomization) evidence of bowel perforation or intra-abdominal abscess.

e. Current or recent colonic diverticulitis. Subject must be adequately treated and off antibiotics for diverticulitis for 60 days prior to randomization.

f. Current colonic adenomas or mucosal dysplasia

i. A subject with adenomatous polyps may be eligible if the polyps have been completely removed or eradicated (documented). The subject must be free of polyps at randomization.

ii. A subject with mucosal dysplasia may be eligible if the dysplasia has been completely removed/resected/eradicated (as applicable, documented), and the subject is free of dysplasia at randomization. This should be discussed with the BMS Medical Monitor/designee prior to screening

iii. Subjects with a history of UC greater than (>) 8 years* duration (who have not had a colonoscopy in the prior 12 months) must have a full colonoscopy at screening.

Subjects who require a colonoscopy to screen for dysplasia (based on local guidelines) must have a full colonoscopy at screening

Subjects who require a colonoscopy to screen for colorectal cancer (based on local guidelines) must have a full colonoscopy at screening.

3.) Gastrointestinal (GI) Surgery Exclusion Criteria

a. History or evidence of extensive colonic resection, subtotal or total colectomy, with or without a stoma or pouch.

b. Current need for, or anticipated need for, surgical intervention for UC during the study.

c. GI surgery within 3 months prior to randomization Subject must have adequate wound healing prior to randomization.

4.) Additional Gastrointestinal (GI) Exclusion Criteria

a. Current or recent (within 12 weeks prior to randomization) GI disease that may confound efficacy assessment or any GI disease associated with poor absorption of the investigational product (for example, untreated celiac sprue, bile salt-mediated diarrhoea, or short bowel syndrome).

b. Receiving enteral feeding, defined formula diets, or total parenteral alimentation.

5.) Immune and Infectious Disease Exclusion Criteria

a. History of congenital or acquired immunodeficiency

b. Known serious infection, defined as any infection requiring hospitalization or treatment with parenteral (intramuscular [IM] or IV) antimicrobial agents (eg, antibiotics, antiviral, antifungal, or antiparasitic agents) within 30 days of the first dose of study treatment. Completion of oral antimicrobial agents within 2 weeks of the first dose of study treatment.

Antibiotics used to cover a procedure such as endoscopy would not exclude the subject.

c. Current or recent (within 12 weeks prior to randomization) herpes zoster, herpes simplex, or influenza infection

d. History of disseminated or complicated herpes zoster infection (including, but not limited to, multi-dermatomal involvement, ophthalmic zoster, central nervous system involvement, or post-herpetic neuralgia)

6.) Prior Concomitant/ Therapy

a. Prior exposure to BMS-986165 or a TYK2 inhibitor

b. Prior treatment failure (inadequate response or loss of response) to medications that target the same pathway as BMS-986165, such as anti-IL-12/IL-23p40 antibodies (eg, ustekinumab, briakinumab) or anti-IL-23p19 antibodies (eg, guselkumab, risankizumab, tildrakizumab, brazikumab [MEDI2070], and mirikizumab [LY3074828]).

Subjects who have been exposed to the medications listed above, but who have not had a treatment failure, may be eligible for inclusion. Similarly, subjects who have experienced intolerance to the medications listed above (eg, an infusion reaction) without a treatment failure may be eligible for inclusion.

c. Prior treatment failure (inadequate response or loss of response) to a JAK inhibitor, such as tofacitinib
Prior exposure to a JAK inhibitor, without treatment failure, is not exclusionary.

d. Current oral prednisone > 20 mg/day (or equivalent) or current budesonide MMX > 9 mg/day (or equivalent)

e. Use of topical rectal treatment with 5-ASA or corticosteroid within 2 weeks prior to randomisation

f. Use of intravenous (IV) corticosteroids within 2 weeks prior to the

screening period

g. Use of immunomodulators (AZA, 6-MP, or MTX) within 4 weeks prior to randomization

h. Use of other investigational agents within 4 weeks or 5 half-lives (whichever is longer) prior to randomization
Faecal transplant is considered an investigational agent for the purpose of this protocol and is subject to a 4-week washout period prior to randomization.

i. Previous stem cell transplantation

j. Use of lymphocyte apheresis or selective monocyte, granulocyte apheresis (eg, Cellsorba*) within 12 months prior to randomization

k. Administration of a live vaccine within 90 days prior to randomization
Live vaccines should not be used during the study or within the 2 months following last dose.
Heat-killed, or otherwise inactivated vaccines, or protein or subunit vaccines (eg, influenza and pneumococcal vaccines) may be received at any time on study. The efficacy of vaccination in subjects who are receiving BMS-986165 is unknown.

l. Currently on any therapy for chronic infection (eg, pneumocystis, cytomegalovirus, herpes simplex, herpes zoster, invasive bacterial or fungal infections, or atypical mycobacteria)

7.) Physical and Laboratory Test Findings

a. Evidence of organ dysfunction or any clinically significant deviation from normal in physical examination, vital signs, ECG, CXR, or clinical laboratory determinations beyond what is consistent with the target population

b. Clinically significant abnormalities on Chest Xray (CXR) or ECG

c. Evidence of active or latent tuberculosis (TB), as follows:

i. History of active TB prior to the screening visit, regardless of completion of adequate treatment
OR

ii. Has signs or symptoms of active TB as judged by the investigator OR CXR obtained during the screening period or anytime within 6 months before screening, with documentation, with evidence of current active or old active pulmonary TB
OR

iii. Latent TB infection (LTBI) defined as positive IFN-γ release assay (IGRA) such as QuantiFERON®-TB Gold, QuantiFERON®-TB Gold Plus, or T-Spot® at screening, or other diagnostic test in the absence of clinical manifestations
OR

iv. An indeterminate IGRA result at screening with no signs or symptoms of active TB

Subjects diagnosed with LTBI during screening may be eligible if (1) there are no current signs or symptoms of active TB and (2) the subject has received adequate documented treatment for LTBI within 5 years of screening OR has initiated prophylactic treatment for LTBI per local guidelines. The subject must now be rescreened after 1 month of treatment. The subject must agree to complete a locally recommended course of treatment for LTBI to continue in the study.

A subject with an indeterminate IGRA test result may be retested within the same screening period. If the second result is also indeterminate, the subject will be excluded from the study. If the second result is positive, the subject should be treated as having LTBI. If the second result is negative, the subject may be eligible provided no other exclusion criterion for TB is met.

d. Evidence of hepatitis B virus (HBV) at screening as defined in the protocol

e. Evidence of hepatitis C virus (HCV) at screening, defined as:

i. Positive for HCV antibody (anti-HCV) and
ii. Positive via a confirmatory test for HCV (eg, detectable

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-06-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BMS-986165
Generic name:	n/a

Ethics review

Approved WMO Date:	20-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
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Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2021
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	13-12-2022
Application type:	Amendment

Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	EUCTR2019-004878-26-NL
CCMO	NL75314.018.20

Study results

Date completed:	27-02-2023
Results posted:	31-05-2024

First publication
01-01-1900