A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of BMS-986165 in Subjects with Moderate to Severe Crohn's Disease

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Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal infections
Study type	Interventional

Summary

ID

NL-OMON52827

Source
ToetsingOnline

Brief title
Safety and Efficacy of BMS-986165 in participants with CD; IM011-023

Condition

- Gastrointestinal infections

Synonym
Crohn's Disease (CD)

Research involving
Human

Sponsors and support

Primary sponsor: Bristol-Myers Squibb

Source(s) of monetary or material Support: Bristol-Myers Squibb

Intervention

Keyword: BMS-986165, Crohn's Disease (CD), Phase 2

Outcome measures

Primary outcome

Primary Efficacy Objectives and Endpoints:

• Objective: To assess the effect of BMS-986165 on clinical remission and endoscopic response at the end of the Induction Period (Week 12 [Day 85])

• Co-primary endpoints:

o Proportion of subjects achieving clinical remission at Week 12, and

o Proportion of subjects achieving endoscopic response at Week 12, both at a population level.

Secondary outcome

Secondary Efficacy Objectives and Endpoints:

• To assess the effect of BMS-986165 on clinical response at the end of the Induction Period

o Endpoint: Proportion of subjects who achieve a clinical response at Week 12

• To assess the effect of BMS-986165 on PRO2 remission at the end of the Induction Period

o Endpoint: Proportion of subjects who achieve PRO2 remission at Week 12

• To assess the effect of BMS-986165 on gut mucosal disease activity by endoscopy at the end of the Induction Period

o Endpoint: Change from baseline in SES-CD at Week 12

The exploratory objectives and endpoints are summarized in Section 4.3.

Study description

Background summary

Tyrosine kinase 2 (TYK2) is a protein involved in interleukin (IL)-12, IL-23 and Type I interferon (IFN) signaling, and it is required for the activation of downstream signaling pathways. TYK2 is a widely expressed, non-receptor tyrosine kinase that catalyzes the phosphorylation of signal transducer and activator of transcription (STAT) proteins downstream of the receptors for the p40-containing cytokines IL-12 and IL-23, as well as the Type I interferon receptor. This results in the activation of STAT-dependent transcription and functional responses specific for these cytokines. TYK2 dependent cytokines (eg, IL-12, IL-23 and Type I IFNs) are distinct from those dependent on closely related Janus kinase (JAK) family members JAK1 and JAK3 (eg, IL 2, IL-6, IL-7, IL-15) or JAK2 (eg, erythropoietin, thrombopoietin, and granulocyte monocyte colony-stimulating factor). Consequently, a TYK2 inhibitor is expected to have a highly differentiated profile from inhibitors of other JAK family kinases. TYK2-dependent pathways and the cytokine networks they modulate (eg, IL-23, IL-17, IFNα) have been implicated in the pathophysiology of multiple immune-mediated diseases, including Crohn*s disease (CD), ulcerative colitis, psoriasis, psoriatic arthritis, systemic lupus erythematosus (SLE) and spondyloarthritides.
BMS-986165 is an orally administered selective TYK2 inhibitor. A comprehensive in vitro and in vivo characterization of BMS-986165 has been established and supports the development of this compound in humans. Inhibition of TYK2 is expected to provide therapeutic benefit for patients with CD for multiple reasons: 1) IL-12 and IL 23 have been implicated in pathogenesis of CD; 2) Biologic agents targeting IL-23p19 and IL 12/23p40 cytokines have been shown to be efficacious in CD, and ustekinumab targeting IL 12/23p40 has been approved for the treatment of CD; and 3) BMS-986165 has been shown to be efficacious in psoriasis, an IL-23-mediated disease, in a recent Phase 2 study.

Study objective

The scientific rationale for the study is summarized above and further detailed in Section 3 and the Investigator Brochure (IB). This Phase 2 randomized, double-blind clinical trial is designed to assess the safety and efficacy of BMS-986165 in patients with moderately to severely active CD. BMS-986165 acts by inhibiting TYK2, a protein involved in IL-12 and IL-23 signaling, in addition to Type I IFN signaling. Briefly, basic and translational studies have implicated IL-12 and IL-23 as potential pathogenic cytokines in intestinal inflammation. Clinical trial programs of biologic medications that inhibit the

IL-12p40 or IL-23p19 cytokine subunits have provided evidence that IL-12p40 inhibition is safe and efficacious in CD, while IL-23p19 inhibition has shown promise in Phase 2 clinical trials in CD.
IL-12 and IL-23 have also been implicated in the pathogenesis of psoriasis. Study IM011011 was a Phase 2 randomized, double-blind clinical trial of BMS-986165 in 267 subjects with moderate to severe psoriasis. In Study IM011011, treatment with BMS-986165 at doses of > 3 mg once daily (QD) were associated with significantly greater clinical responses compared with placebo at Week 12, as measured by a >= 75% reduction in the Psoriasis Area and Severity Index (PASI, PASI 75) score. At Week 12, the percentage of patients with a PASI 75 response was 7% (3 of 45 patients) with placebo, 39% (17 of 44 patients) with 3 mg QD, 69% (31 of 45 patients) with 3 mg BID, 67% (30 of 45 patients) with 6 mg BID, and 75% (33 of 44 patients) with 12 mg QD (P value < 0.001 for each comparison). Treatment with BMS-986165 at doses > 3 mg BID was also associated with a numerically greater proportion of patients achieving >= 90% reduction in PASI score (PASI 90), compared with placebo at Week 12. This study provides a proof of concept that BMS-986165 may be effective in the treatment of an IL-23 mediated disease in humans. Taken together, these data provide a scientific rationale for studying BMS-986165 in CD.
The eligibility criteria are designed to ensure that subjects have moderately to severely active CD at baseline and to minimize the risk for serious infections that may be associated with immune modulating therapies.
Clinical disease activity is assessed in this study using the CDAI. CDAI is a composite instrument that includes patient-reported abdominal pain (AP), stool frequency (SF), general well-being, presence of complications of CD, hematocrit, weight, presence of a CD-related abdominal mass, and the use of antidiarrheal medication. CDAI has been widely used in registrational clinical trial programs, but does have certain limitations: eg, (i) the AP and SF components are weighted, (ii) the CDAI incorporates items that are not patient-reported outcomes (PROs), (iii) the CDAI does not include an assessment of mucosal inflammation, and (iv) the CDAI does not correlate well with endoscopic findings. In order to address these limitations, a PRO2 instrument that includes unweighted AP and SF will be evaluated during the study, and mucosal inflammation will also be assessed by endoscopy and histology.
Mucosal disease activity is assessed in this study using the Simple Endoscopic Score for Crohn's Disease (SES-CD). Clinical symptoms assessed by CDAI only have a modest correlation with objective evidence of mucosal inflammation, assessed by SES-CD. Consequently, in order to evaluate if BMS-986165 is effective at improving both the clinical symptoms of CD and objective evidence of mucosal inflammation, clinical remission (based on CDAI) and endoscopic response (based on SES-CD) will be used as co-primary endpoints at Week 12, on a population basis. The SES-CD will be assessed by a blinded central reader.
Additional endpoints of interest include CDAI-based clinical response, PRO2 remission, endoscopic remission, endoscopic normalization, deep remission (clinical plus endoscopic remissions), histological endpoints, patient reported measures of disease control and quality of life improvement, and measurement of pharmacodynamic (PD) responses. The ability to measure biomarkers in peripheral

blood and gut tissue specimens from patients with CD both before and after treatment allows for evaluation of target-specific and disease-specific PD measures in the relevant tissues over time.
IM011023 is the first clinical trial of BMS-986165 in patients with active CD. In order to explore the dose-response relationship of BMS-986165 in this patient population, 2 dose regimens of BMS 986165 are included in this study, in addition to a placebo arm. As substantial placebo responses have been observed in previous CD clinical trials, the placebo arm provides an important control for potential confounding factors derived from natural variability in the clinical course of CD, and from potentially confounding effects of standard medical care, as well as to provide a benchmark for safety. The number of subjects exposed to placebo has been minimized (3:1 ratio of BMS 986165:placebo, overall), with provision for treatment of placebo non-responders at Week 12 with BMS-986165 at the higher dose of 6 mg BID. Subjects will also be allowed to continue 5 aminosalicylates (5 ASAs), probiotics, CD-targeted antibiotics, and/or corticosteroids (subject to dose stabilization requirements) through Week 12 (Day 85). In addition, 5-ASAs, probiotics, and CD-related antibiotics can continue throughout the duration of the study (104 weeks in total).
Corticosteroids (prednisone up to 20 mg/day or equivalent) are allowed in the Induction Period of the study, subject to dose stabilization requirements. Subjects who achieve clinical response at Week 12 must taper corticosteroids in the Maintenance Period according to the tapering schedule in Section 5.1.4.2, unless they exhibit signs or symptoms of adrenal insufficiency. This approach limits the total duration of corticosteroid exposure for study subjects and facilitates an exploratory analysis of whether treatment with BMS-986165 is associated with corticosteroid-free efficacy in the Maintenance Period.
Randomization stratified by concomitant corticosteroid use, region, and prior/current exposure to TNFi (ie, TNFi exposed or TNFi naïve) is being implemented to distribute subjects equally across treatment groups (except in Japan) based on these characteristics (Section 5.1.2), which may indicate the background severity of disease and/or background level of disease control, and to balance for potential regional differences in CD background medication. There will be separate strata for Japan; however, the other stratification factors (TNFi and concomitant corticosteroid use) will not be applied.
A justification for dose and regimen and a benefit/risk assessment are provided in Section 3.2.2 and Section 3.2.3, respectively.

Study design

IM011023 is a Phase 2 randomized, double-blind, placebo-controlled clinical study designed to assess the safety and efficacy of BMS 986165 compared to placebo in subjects with moderately to severely active CD.
Approximately 240 subjects will be randomized in this study. After a 28-day Screening Period, eligible subjects will be randomized in a 3:3:2 ratio to one of three study arms: (i) BMS 986165 6 mg twice daily (BID) by mouth (PO); n*90, (ii) BMS-986165 3 mg BID PO; n*90, or (iii) matched placebo; n*60.

Randomization will be stratified according to geographic region (US, Japan, Rest of World), prior exposure to tumor necrosis factor inhibitor (TNFi; Exposed/Naïve), and concomitant corticosteroid use (yes/no). Since the number of subjects from Japan is expected to be small, the stratification factors of prior exposure to TNFi and concomitant corticosteroid use will not be applied in Japan.
This study has a 12-week double-blind Induction Period, a 40-week double-blind Maintenance Period, and a 52-week Open label Extension (OLE) Period, leading to a total of up to 104 weeks of exposure to investigational product (IP). The primary efficacy assessment occurs at Week 12. The co-primary endpoints are defined as achieving clinical remission (defined as Crohn*s Disease Activity Index [CDAI] of < 150) and achieving endoscopic response (>= 50% improvement from baseline in the Simple Endoscopic Score for Crohn*s Disease [SES CD]), on a population basis, at Week 12.
This study has a treat-through design in order to explore sustained clinical benefit and safety in the Maintenance Period. Subjects who achieve clinical response (a reduction from baseline in the CDAI score of >= 100 points or a total CDAI score < 150) at Week 12 (Day 85), are eligible to enter the Maintenance Period and to continue on the same double-blind treatment regimen that they received in the Induction Period for up to an additional 40 weeks, up to Week 52. Subjects with a loss of response (LOR; an increase in the CDAI score of >= 100 points compared to Week 12 and a total CDAI score of >= 220 points) at any time from Week 13 through Week 52 are eligible to enter an open-label BMS-986165 6 mg BID PO arm through Week 52.
Subjects who do not achieve clinical response at Week 12 are eligible to enter an open-label BMS 986165 6 mg BID PO arm. In this study arm, clinical response is assessed at Week 26. Subjects who achieve clinical response at Week 26 may continue in this arm through Week 52. Subjects who do not achieve clinical response at Week 26 must discontinue IP and enter the Post treatment Follow-up Period. Throughout the study, subjects who permanently discontinue IP prior to Week 52 must enter the Post-treatment Follow-up Period.
Subjects who continue to derive a clinical benefit from IP at Week 52, as judged by the investigator, are eligible to enter the OLE Period. The OLE Period lasts 52 weeks, to Week 104.

Intervention

Subjects will be assigned into a group to receive either BMS-986165 or placebo. The chances of receiving BMS-986165 are 2 in 3 (67%). They will be assigned randomly to receive BMS-986165 or placebo, as oral capsules, at one of the following doses:
• 6 mg twice daily or
• 3 mg twice daily or
• placebo twice daily
The doses will be arranged into sets of 4 capsules and you will have to take them in the morning and in the evening, approximately 12 hours apart.

Study burden and risks

See ICF section 7.0.

Contacts

Public
Bristol-Myers Squibb

Chaussée de la Hulpe 185
Brussels 1170
BE
Scientific
Bristol-Myers Squibb

Chaussée de la Hulpe 185
Brussels 1170
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Signed Written Informed Consent
a) Willing to participate in the study and sign the ICF.
b) Willing and able to complete all study-specific procedures and visits.
2) Type of Subject and Target Disease Characteristics
a) Not applicable per Global Revised Protocol v3.0
b) Not applicable per Global Revised Protocol v3.0

c) Not applicable per Global Revised Protocol v3.0
d) Not applicable per Global Revised Protocol v3.0
e) Documented diagnosis of CD for at least 3 months prior to screening, including ileal, colonic, or ileo-colonic disease distribution, confirmed by:
• Source: Medical records with report of a colonoscopy with ileal intubation (ileocolonoscopy), which shows features consistent with CD, as determined by the procedure performing physician, AND
• Source: Medical record documentation of a histopathology report showing features consistent with CD, as determined by the local pathologist.
Note: If a histopathology report is not available, histologic samples can be obtained at the screening endoscopy and sent to a local laboratory to confirm diagnosis of CD before proceeding to randomization. The screening endoscopy must show features consistent with CD.
f) Must have active moderate to severe CD, as defined by:
• CDAI score of 220 to 450 AND
• PRO2: Average daily score for abdominal pain >= 2 OR average daily number of very soft (loose) or liquid (watery) stools (BSS Type 6 or 7 only; see APPENDIX 18) >= 4, (see Section 9.1), AND
• Evidence of active inflammation in at least 1 of the 5 ileocolonic segments (based on central reading) with total SES-CD >= 6 or SES-CD >= 4 if only isolated ileitis is present on baseline endoscopy
g) Must have had an inadequate response, LOR, or intolerance to a standard treatment course of 1 or more of the following medications as below:
• Oral 5-ASAs: (eg, mesalamine, sulfasalazine, olsalazine, balsalazine) at or above the approved label dose (or per local standard of care) for induction therapy for at least 6 weeks
• Oral corticosteroids: Prednisone >= 40 mg/day or equivalent for 2 weeks, or 2 failed attempts to taper oral corticosteroids below prednisone or equivalent 10 mg daily, or a relapse within 3 months of discontinuing corticosteroids
• Intravenous (IV) corticosteroids: hydrocortisone >= 400 mg/day or equivalent for at least 1 week
• Immunomodulators: AZA >= 1.5 mg/kg/day, 6-MP >= 0.75 mg/kg/day, MTX >= 15 mg/week, or as per Institutional Practice/Country-approved label or guideline, for at least 12 weeks. At institutions that utilize thiopurine levels in clinical practice: AZA or 6-MP prescribed for at least 12 weeks with at least 1 demonstration of therapeutic thiopurine metabolite levels. Note: subjects with defined NUDT15 or TPMT mutations who experience intolerance to thiopurines at lower doses than those listed above may be eligible for this study. This should be discussed with the medical monitor on a case-by-case basis.
• Biologics: (eg, infliximab, adalimumab, certolizumab pegol, vedolizumab, natalizumab, ustekinumab) as defined in APPENDIX 4. Subjects can be included if treatment with a biologic was stopped due to primary or secondary nonresponse, or were intolerant to treatment, as defined in APPENDIX 4.
3) Age and Reproductive Status
a) Men and women aged 18 to 75 years inclusive at the time of screening
b) Women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of beta-human

chorionic gonadotropin) within 24 hours prior to the start of study treatment.
c) Women must not be breastfeeding
d) Not applicable per Global Revised Protocol v3.0
e) Not applicable per Global Revised Protocol v3.0
f) Not applicable per Global Revised Protocol v3.0
g) Not applicable per Global Revised Protocol v3.0
h) Azoospermic males are exempt from contraceptive requirements. WOCBP who are continuously not heterosexually active are also exempt from contraceptive requirements, and still must undergo pregnancy testing as described in this section.
i) Not applicable per Global Revised Protocol v3.0
j) Not applicable per Global Revised Protocol v5.0
k) Investigators shall counsel WOCBP and men who are sexually active with WOCBP on the importance of pregnancy prevention and the implications of an unexpected pregnancy. Investigators shall advise on the use of methods of contraception (APPENDIX 5).
l) Male subjects should maintain their usual practice with regards to contraception (if any). However, no specific additional contraceptive measures are required.
m) WOCBP must agree to at least an acceptable, less than highly effective means of contraception (see APPENDIX 5) for the duration of treatment with study treatment(s) (BMS-986165 or placebo).

Exclusion criteria

1) Target Population
a) Severe or fulminant colitis that is likely to require surgery or hospitalization
b) Presence of a diagnosis of alternative forms of colitis (infectious, inflammatory including ulcerative colitis, malignant, toxic, indeterminate, etc) other than CD
c) Not applicable per Global Revised Protocol v3.0
d) History of intra-abdominal abscess within the last 60 days
• Previous intra-abdominal abscess that has been drained and successfully treated with a local standard course of antimicrobial therapy is permitted (the course must be completed at least 60 days prior to Day 1)
e) History of diverticulitis within the last 60 days
• Previous diverticulitis that has been successfully treated with a local standard course of antimicrobial therapy is permitted. (the course must be completed at least 60 days prior to Day 1)
f) Receiving tube feeding, defined formula diets, or total parenteral alimentation
g) Current colonic dysplasia or past colonic dysplasia that has not been definitively treated
h) History of infectious (bacterial, viral, fungal, parasitic, etc.) colitis

within past 30 days; must be fully treated to rescreen
i) Use of therapeutic enema or suppository, other than required for ileocolonoscopy, within 7 days prior to screening or during the Screening Period
j) Not applicable per Global Revised Protocol v3.0
k) Not applicable per Global Revised Protocol v3.0
l) Previous exposure to BMS-986165 in any study
m) Not applicable per Global Revised Protocol v.5.0
n) Not applicable per Global Revised Protocol v3.0
o) Not applicable per Global Revised Protocol v.5.0
p) Prior treatment with specific lymphocyte-depleting agents, such as alemtuzumab and rituximab, are prohibited within 12 months prior to the first dose of study treatment during the Induction Period.
q) Receipt of either lymphocyte apheresis or selective monocyte, granulocyte apheresis (eg, Cellsorba*) is prohibited within 12 months prior to the first dose of study treatment during the Induction Period.
r) Previous treatment with investigational agents within 4 weeks or 5 half-lives (whichever is longer) prior to the first dose of study treatment during the Induction Period. Subjects treated with investigational agents 4 to 12 weeks prior to the first dose of study treatment must be discussed with the medical monitor.
s) Previous stem cell transplantation, (except local stem cell therapy to treat perianal fistulae (eg, Alofisel® [darvadstrocel]). Please discuss on a case by case basis with the medical monitor.
t) Presence of a stoma, gastric or ileoanal pouch, previous proctocolectomy or total colectomy, or symptomatic, stenosing disease that is likely to confound efficacy assessment (eg, symptomatic CD-related stricture), abscess or suspected abscess, pouchitis, short bowel syndrome, or history of bowel perforation. In addition, subjects with colonic or ileal strictures that are not passable via colonoscope that the endoscopist normally uses in clinical practice, or strictures in the ileum or ileocecal valve that are fibrotic in nature, will be excluded.
2) Other Medical Conditions and History
a) Women who are pregnant or breastfeeding
b) Any major illness/condition or evidence of an unstable clinical condition (eg, renal, hepatic, hematologic, gastrointestinal, endocrine, pulmonary, immunologic, psychiatric, or local active infection/infectious illness) that, in the investigator*s judgment, will substantially increase the risk to the subject if he or she participates in the study
c) Any major surgery within the last 30 days before the first dose of study treatment, or any surgery planned during the course of the study
d) Not applicable per Global Revised Protocol v3.0
e) Female subjects with a breast cancer screen suspicious for malignancy, and in whom the possibility of malignancy cannot be reasonably excluded after additional clinical, laboratory, or other diagnostic evaluations
f) Significant blood loss (> 500 mL) or blood transfusion within 4 weeks of study treatment administration
g) Inability to tolerate oral medication

h) Inability to undergo venipuncture and/or tolerate venous access
i) Not applicable per Global Revised Protocol v3.0
j) Any other sound medical, psychiatric, and/or social reason as determined by the investigator
k) Potential subjects with the following characteristics will be excluded from the study:
• History of any kind of bowel resection within 6 months or any other intra-abdominal surgery within 3 months prior to baseline
• History of any surgical procedure requiring general anesthesia, other than required for ileocolonoscopy, within 30 days prior to the first dose of study treatment, or is planning to undergo surgery during the study period
• History of bleeding disorders or recent use of anti-platelet or anti-thrombotic agents that in the investigator*s judgment preclude safely performing endoscopic procedures and biopsy within the timeframe outlined in the study protocol
• Currently on any therapy for chronic infection (eg, pneumocystis, cytomegalovirus, herpes simplex, herpes zoster, invasive bacterial or fungal infections, or atypical mycobacteria)
• History of congenital or acquired immunodeficiency
• 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, or 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.
o In the case of prior SARS-CoV-2 infection, symptoms must have completely resolved 4 weeks prior to screening and based on investigator assessment in consultation with the medical monitor, there are no sequelae that would place the subject at a higher risk of receiving BMS-986165. See Section 9.10 for additional information regarding retesting subjects who have had prior SARS-CoV-2 infection.
• Previous history of herpes zoster, herpes simplex, or influenza infection within 12 weeks before the first dose of study treatment or a history of disseminated/complicated herpes zoster infection (multidermatomal involvement, ophthalmic zoster, central nervous system involvement, or post-herpetic neuralgia)
• Cancer or history of cancer or lymphoproliferative disease within the previous 5 years (other than adequately treated cutaneous basal cell or squamous cell carcinoma or resected cervix carcinoma in situ with no evidence of recurrence)
• Class III or IV congestive heart failure, as classified by the New York Heart Association (NYHA) Functional Classification or any recent onset of heart failure resulting in NYHA Class III/IV symptoms
• Acute coronary syndrome (eg, myocardial infarction, unstable angina pectoris) and/or any history of significant cerebrovascular disease (eg, stroke, cerebral hemorrhage, transient ischemic attack) within 24 weeks before screening
• Administration of a live vaccine within 90 days before the first dose of

study treatment administration. Heat-killed, or otherwise inactivated, protein or subunit vaccines (eg, influenza and pneumococcal vaccines), nucleic acid vaccines that do not encode potentially infectious virus, and replication incompetent recombinant vector vaccines may be received at any time on study. Furthermore, live vaccines should not be used during the study and within the 2 months following last dose, and any other inactivated vaccines (eg, tetanus, etc.) should be used according to local guidelines during the treatment period.
• Current or recent (within 3 months before the first dose) gastrointestinal disease, including gastrointestinal surgery, that could impact the absorption
o

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:	Completed
Start date (anticipated):	06-01-2022
Enrollment:	3
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BMS-986165
Generic name:	6-[(cyclopropylcarbonyl)amino]-4-{[2-methoxy-3-(1-methyl-1H-1,2,4-triazol-3-yl)phenyl]amino}-N-(2H3)

Ethics review

Approved WMO Date:	08-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2022
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	EUCTR2017-001976-48-NL
ClinicalTrials.gov	NCT03599622
CCMO	NL74546.018.20

Study results

Date completed: 20-07-2022

Results posted: 11-06-2024

First publication
24-05-2024