A Phase 3, Multicenter, Multinational, Randomized, Open-Label, Parallel-Arm Study of Avelumab* (MSB0010718C) plus Best Supportive Care Versus Best Supportive Care Alone as a Maintenance Treatment in Patients with Locally Advanced or Metastatic Urothelial Cancer whose Disease did not Progress after Completion of First-Line Platinum-Containing Chemotherapy

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To demonstrate the benefit of maintenance treatment with avelumab plus BSC vs. BSC alone in prolonging overall survival (OS) in patients with unresectable locally advanced or metastatic UC whose disease did not progress on or following completion of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55699

Source
ToetsingOnline

Brief title
JAVELIN Bladder 100

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
Urothelial cancer

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: Avelumab, Best suportive care, Urothelial cancer (UC)

Outcome measures

Primary outcome

Overall Survival (OS).

Secondary outcome

* Progression free survival (PFS) based on Blinded Independent Central Review

(BICR) assessment per RECIST v1.1.

* Investigator assessed Progression-Free Survival (PFS). Objective Response

(OR), Time to Tumor Response (TTR), Duration of Response (DR), and Disease

Control (DC), as assessed per RECIST v1.1 by BICR and investigator.

* Safety: Adverse events (AEs) and laboratory abnormalities as graded by

National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events

(CTCAE) v.4.03; vital signs (blood pressure, pulse rate).

* Pharmacokinetics (PK): maximum concentrations (Cmax) and trough

concentrations (Ctrough) for avelumab.

* Immunogenicity: Anti-drug antibodies (ADA; neutralizing antibody [Nab])

against avelumab.

* Biomarkers: Tumor tissue biomarkers including, but not limited to, PD-L1

expression and tumor-infiltrating CD8+ T lymphocytes.

* Patient-Reported Outcomes: patient-reported bladder cancer symptom,

functioning, global quality of life (QOL), and Time to Deterioration (TTD)

using the NCCN-FACT FBlSI-18; and health status using the EQ-5D.

Study description

Background summary

Urothelial cancer (UC) includes tumors originating from the urothelial cells lining the bladder, renal pelvis, ureter, and urethra. Bladder cancer alone accounts for 90% of UC, and is the ninth most prevalent cancer worldwide, with approximately 400,000 new cases diagnosed and 150,000 deaths attributed to this disease each year. UC occurs more frequently in developed countries; in Europe it is the eighth most common cause of mortality due to cancer, and in the United States, it also occurs at a very high annual incidence rate (20.5 per 100,000 persons).The incidence and mortality of bladder cancer have remained unchanged over the last 25 years.

Combination chemotherapy with platinum-based regimens is the standard of care for locally advanced or metastatic bladder cancer. Despite the favorable response and survival rates associated with the combination of methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) toxicities associated with this regimen can be significant and lead to death in 3-4% of patients.Subsequently, the combinations of gemcitabine + cisplatin and gemcitabine + carboplatin were shown to have comparable efficacy and an improved safety compared to MVAC, with the latter combination used in the 30 50% of patients ineligible for cisplatin based chemotherapy due to renal impairment. As such, these two regimens are now the preferred regimens for the initial treatment of patients with locally advanced or metastatic UC.

Durable and complete responses following first-line chemotherapy in patients with advanced UC are uncommon. Complicated treatment regimens and severe side effects limit long-term use of these agents and most patients will ultimately experience disease progression within 9 months after initial response. Optimal

treatment in the second-line treatment setting still needs to be determined.20 In the United States, no second-line therapies have been approved. Single and combination agents evaluated in this treatment setting have been associated with low median progression-free survival (PFS, 1.5-3.0 months) and overall survival (OS, 4.6. 6.9 months), and are also associated with significant toxicities.
In 2009, vinflunine was approved in Europe for the second-line treatment of UC after failure of first-line platinum-based therapy.

The current *watch-and-wait* approach for the management of metastatic UC following response to first line chemotherapy prior to initiation of second-line treatment has not proven to be effective because almost all patients eventually relapse. A multicenter Phase 2 study of sunitinib as maintenance therapy in patients with advanced UC was recently reported.25 Although the study terminated prematurely due to low patient recruitment, it provided a different perspective on the treatment of this disease (ie, maintenance therapy following response to first-line chemotherapy in an attempt to improve the durability of the initial response). Recently, Powles et al reported the results of a Phase 2/3 study of lapatinib as maintenance treatment after first-line chemotherapy in patients with HER1/HER2 positive UC.26 The median PFS, median OS, and objective response rate (ORR) for patients receiving lapatinib (n = 116) vs. placebo (n = 116) were 4.6 months (95% confidence interval [CI]: 2.8 * 5.4) vs. 5.3 months (95% CI: 3.0 * 5.9) (hazard ratio [HR] 1.04 [95% CI: 0.79 * 1.39] p = 0.77), and 12.6 months (95% CI: 9.5 * 16.2) vs. 11.9 months (95% CI: 10.6 * 15.8) (HR 0.98 [95% CI: 0.71 * 1.35] p = 0.89); and 13.8% vs. 7.8%, respectively (p = 0.14). In addition, a study evaluating vinflunine27,28 as a maintenance UC treatment is currently ongoing.

Study objective

To demonstrate the benefit of maintenance treatment with avelumab plus BSC vs. BSC alone in prolonging overall survival (OS) in patients with unresectable locally advanced or metastatic UC whose disease did not progress on or following completion of first line platinum containing chemotherapy in each co primary UC patient population: 1) patients determined to have PD L1 positive tumors (including infiltrating immune cells) by a verified GMP PD L1 IHC test, and 2) all randomized patients.

Secondary Objectives
* To compare the PFS of avelumab plus BSC vs. BSC alone in patients determined to have PD L1 positive tumors (including infiltrating immune cells) by a verified GMP PD L1 IHC test, and in all randomized patients.
* To evaluate the anti-tumor activity of avelumab plus BSC and BSC alone according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 in patients determined to have PD L1 positive tumors (including infiltrating immune cells) by a verified GMP PD L1 IHC test, and in all randomized patients.
* To evaluate the overall safety profile of avelumab plus BSC and BSC alone.

* To evaluate the pharmacokinetics (PK) of avelumab in each of the co-primary populations treated with avelumab.
* To assess the immunogenicity of avelumab in each of the co-primary populations treated with avelumab.
* To evaluate candidate predictive biomarkers of sensitivity or resistance to avelumab in pre-treatment tumor tissue in each of the co-primary populations treated with avelumab.
* To evaluate the effect of avelumab plus BSC and BSC alone on patient-reported outcomes (PROs) in each of the co-primary populations.
Exploratory Objectives
* To explore the predictive and/or pharmacodynamic (PD) characteristics of peripheral blood and additional tumor tissue biomarkers relevant to the mechanism of action of or resistance to avelumab.
* To explore the anti-tumor activity of avelumab plus BSC and BSC alone in each of the co primary UC patient populations according to immune-related RECIST (irRECIST).50

Study design

Patients randomized to avelumab plus BSC (Arm A) will be administered avelumab as a 1-hour intravenous (IV) infusion at a dose of 10 mg/kg once every 2 weeks (Q2W) together with BSC (see below).
To mitigate potential infusion-related reactions, patients in Arm A will be premedicated prior to avelumab administration as described in . If an infusion related reaction is observed, the infusion rate should be decreased to a maximum infusion time of 120 minutes

* Arm B: Best Supportive Care Alone
Patients randomized to BSC alone (Arm B) will be cared for as deemed appropriate by the treating physician. This could include treatment with antibiotics, nutritional support, correction of metabolic disorders, optimal symptom control and pain management (including palliative radiotherapy), etc. BSC does not include any active anti-tumor therapy, however local radiotherapy of isolated lesions with palliative intent is acceptable.

All patients will be followed for survival until death, end of the study, or patient withdrawal of consent, whichever comes first, regardless of initiation of new anti cancer therapy(ies). Long term follow up survival assessments (every 3 months) may be completed at the investigative site or by telephone contact.

Intervention

Avelumab will be given as an intravenous infusion, over 1 hour, every 2 weeks.The infusion will occur during clinic visits under close supervision of yhe study doctor and their staff. About 30-60 minutes before each dose of

Avelumab, patients will also receive either by mouth or intravenously an anti-histamine (H1 blocker) and acetaminophen (also called paracetamol). This is to help reduce the risk of an allergic reaction to Avelumab.

Study burden and risks

Side effects observed in 10% or more of patients:
* General signs or symptoms: Tiredness; Nausea; Loose or watery stools (diarrhea); Constipation; Reduced appetite; Decrease in weight; Vomiting; Low number of red blood cells (anemia); Belly pain; Cough; Fever; Shortness of breath; Swelling of feet and legs; Back pain; Joint pain.
* Reactions that occur during or following the infusion: may include chills or shaking, fever, flushing, back pain, belly pain, shortness of breath or wheezing, decrease in blood pressure, hives. These infusion reactions are mostly mild or moderate and generally resolve with a slowdown or discontinuation of the infusion and administration of medications such as anti-allergic and pain-killer drugs. In some cases these reactions may be severe or life-threatening (in less than 1% of patients) and can require intensive medical care.

Immune side effects

Immune side effects observed in 5% to less than 10% of patients
* Abnormal function of the thyroid gland (could include low or high function or inflammation of the thyroid gland): may include rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; hair loss; changes in mood or behavior such as irritability or forgetfulness; feeling cold; constipation; voice gets deeper.
* Inflammation of the skin (rash): may include skin rash, itchy skin, skin redness, skin blisters, or peeling.

Immune side effects observed in 1% to less than 5% of patients
* Inflammation of the large intestine (colitis): may include diarrhea (loose stools) or more frequent bowel movements than usual; blood in stools or dark, tarry, sticky stools; severe stomach area (abdomen) pain or tenderness.
* Inflammation of the lungs (pneumonitis): may include new or worsening cough, shortness of breath, chest pain.
Immune side observed in less than 1% of patients:
* Inflammation of the liver (hepatitis): may include yellowing of skin or of the whites of eyes; severe nausea or vomiting; pain on the right side of stomach area (abdomen); drowsiness; dark urine (tea colored); bleeding or bruising more easily than normal; feeling less hungry than usual.
* Inflammation of the kidneys (nephritis): may include urinating less than usual; blood in urine; swelling in ankles; loss of appetite.
* Low function of the adrenal glands (glands on top of the kidneys), which may be due to the reduced function of the pituitary gland (a gland in the head): may include very low blood pressure; extreme tiredness.

* Increase in blood sugar (diabetes): may include urinating more often than usual; feeling more hungry or thirsty than usual, nausea or vomiting, stomach area (abdomen) pain.
* Inflammation of the eyes (uveitis): may include changes in eyesight.
* Inflammation of the muscles (myositis): may include severe or persistent muscle or joint pain; severe muscle weakness.
* Inflammation of the heart (myocarditis): may include chest pain or tightness; tiredness; changes in heartbeat, such as beating fast, or seeming to skip a beat, or pounding sensation; swelling of feet and legs; trouble breathing.
* Inflammation of the nerves (Guillain-Barre syndrome): may include "pins and needles" sensations in arms and legs; weakness in legs that spreads to the upper body and may lead to temporary paralysis.

Risks from Study Procedures
* Blood samples: A blood draw may cause inflammation of the vein, pain, bruising, discomfort redness, burning or bleeding at the site where the needle is placed to draw the blood. You may feel dizzy or you may faint. There is a slight chance of infection.
* Intravenous Catheter: The use of an intravenous catheter may cause pain, bruising, clotting, bleeding, leakage of drug solution, and possibly infection at the catheter site.
* ECG: The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the patches.
* Questionnaires: A questionnaire may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you should contact your study doctor.
* Bone Scan: A bone scan exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, this amount of radiation should not create a significant risk to your health.
* CT scans: You may experience fear of being in a narrow or enclosed space while having a CT scan. You will be asked not to move during the test and to relax and breathe normally. A CT scan exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, this amount of radiation should not create a significant risk to your health.
* MRI Scans: There are risks from an MRI if you are pregnant or have one of the following: an artificial heart valve, pacemaker, metal plate, pin or other metallic objects in your body (including gun shot or shrapnel). You may also become anxious from lying in a tight space without moving. The MRI scan does not cause any pain and does not expose you to x-ray radiation.
* Contrast Dye for CT & MRI Scans: Contrast dye is usually injected when you get a scan. A contrast dye may cause pain or burning when it is injected, and may worsen kidney function in people who already have kidney disease or who are dehydrated (have not had enough liquids that day). The contrast dye may also cause allergic reactions, which could be severe or life-threatening.
* Biopsy: The risks of a biopsy can include bleeding, pain and infection. To

reduce these risks, the site of the biopsy will be numbed and sterile techniques will be used.
* Genetic Research Risks: The pharmacogenomics / biomarker research that may be performed using your tissue and blood samples may involve genetic testing. Although procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you, there is a remote possibility that information from your participation in this study could adversely affect you or your family in some way if a genetic disorder were discovered.

Contacts

Public
Pfizer

E 42nd Street 235
New York, NY 10017
US
Scientific
Pfizer

E 42nd Street 235
New York, NY 10017
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Histological diagnosis of confirmed, unresectable locally advanced or

metastatic transitional cell carcinoma of the urothelium. patients with documented Stage IV disease (per American Joint Committee on cancer/International Union for Cancer Control Tumor Node Metastasis (TNM) system 7th edition) at the start of first-line chemotherapy and measurable disease prior to the start of first-line chemotherapy by RECIST v1.1., 2. Prior first-line chemotherapy must have consisted of at least 4 cycles and no more than 6 cycles of gemcitabine + cisplatin and/or gemcitabine + carboplatin. No other chemotherapy regimens are allowed in this study. The last dose of first-line chemotherapy must have been recieved no less than 4 weeks, and no more than 10 weeks, prior to randomization; , 3. Patients without progressive disease as per RECIST v1.1 guidelines (ie, with an ongoing CR, PR, or SD) following completion of 4 to 6 cycles of first-line chemotherapy. Eligibility based on this criterion will be determined by investigator review of pre-chemotherapy and post-chemotherapy radiological assessments (CT/MRI scans);, 4. Provision of a recent formalin-fixed, paraffin-embedded (FFPE) tumor tissue block (subsection thereof) from the most recent primary or metastatic tumor biopsy or resection obtained prior to treatment with first line chemotherapy but within 24 monthsof randomization, with no intervening systemic anti-cancer therapy. If a FFPE tissue block cannot be provided 15 freshly cut unstained slides (10 minimum) will be acceptable. Tumor tissue from cytologic sampling (eg, fine needle aspiration, including FFPE cell pellet material) or bone metastases are not acceptable and should not be sumbitted;, 5. Evidence of a signed and dated informed consent document indicating that the patient (or a legally acceptable representative, as allowed by local guideline/practice) has been informed of all pertinent aspects of the study, , 6. Patients who are willing and able to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures;, 7. Age above 18 years;, 8. Estimated life expectancy of at least 3 months; , 9. Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1; , 10. Adequate bone marrow, renal and liver function; , 11. Negative serum pregnancy test at screening (for females of childbearing potential); , 12. Female patients able to have children must agree to use a highly effective method of contraception throughout the study and for at least 30 days after the last dose of assigned treatment.

Exclusion criteria

1. Patients whose disease progressed by RECIST v1.1 on or after first-line chemotherapy for urothelial cancer; , 2. Prior adjuvant or neoadjuvant (systemic) therapy within 12 months of randomization; , 3. Prior immunotherapy with IL-2, IFN-*, or an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or CTLA-4 antibody (including ipilimumab), or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways;, 4. Major surgery within 4 weeks or major radiation therapy within 2 weeks prior to randomization. Prior palliative radiotherapy (<= 10 fractions) to metastatic

lesion(s) is permitted, provided it has been completed at least 48 hours prior to patient randomization;, 5. Patients with known symptomatic central nervous system (CNS) metastases requiring steroids. Patients with previously diagnosed CNS metastases are eligible if they have completed their treatment and have recovered from the acute effects of radiation therapy or surgery prior to randomization, have discontinued corticosteroid treatment for these metastases for at least 4 weeks, and are neurologically stable;, 6. Persisting toxicity related to prior therapy NCI CTCAE v4.0 Grade >1; however, alopecia, sensory neuropathy Grade <= 2 is acceptable, or other grade <= adverse events not constituting a sefetey risk based on the investigator's judgement are acceptable;, 7. Diagnosis of any other malignancy within 5 years prior to randomization, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ of the breast or of the cervix, or low-grade (Gleason 6 or below) prostate cancer on surveillance without any plans for treatment intervention (eg, surgery, radiation, or castration), or prostate cancer that had been adequatley treated with prostatectomy or radiotherapy and currentley with no evidence of disease or symptoms;, 8. Participation in other studies involving investigational drug(s) within 4 weeks prior to randomization. Observational studies are permitted;, 9. Active autoimmune disease that might deteriorate when receiving an, immunostimulatory agent. Patients with diabetes type I, vitiligo, psoriasis, or hypo- or hyperthyroid disease not requiring immunosuppressive treatment are eligible;, 10. Clinically significant (ie, active) cardiovascular disease; cerebral vascular accident/stroke (<6 months prior to enrolment), myocardial infarction (<6months prior to enrolment), unstable angina, congestive heart failure, or serious cardiac arrhythmia requiring medication;
11. Active infection requiring systemic therapy;, 12. Known severe hypersensitivity reactions to monoclonal antibodies (Grade >= 3), any history of anaphylaxis, or uncontrolled asthma;, 13. Known prior or suspected hypersensitivity to study drugs or any component in their formulations;, 14. Current or prior use of immunosuppressive medication within 7 days prior to randomization;, 15. Diagnosis of prior immunodeficiency or organ transplant requiring immunosuppressive therapy. 16. Positive test for human immunodeficiency virus (HIV) infection or know acquired immunodeficiency syndrome (AIDS)
17. Hepatitis B virus (HBV) or hepatitis C virus (HCV) at screening;, 18. Vaccination within 4 weeks of the first dose of study treatment and while on trial is prohibited except for administration of inactivate vaccines (for example, inactivated influenza vaccines); , 19. Patients who are investigational site staff members directly involved in the conduct of the study and their family members, site staff members otherwise supervised by the investigator, or patients who are Pfizer employees directly involved in the conduct of the study;
20. Pregnant female patients; breastfeeding female patients and female patients of childbearing potential who are unwilling or unable to use a highly effective method of contraception as outlined in the protocol for the duration of the study and for at least 30 days after the last dose of investigational product;

21. Other severe acute or chronic medical conditions including colitis, inflammatory bowel disease, and pneumonitis and pulmonary fybrosis; psychiatric condition including recent (within the past year) or active suicidal ideation or behavior; or laboratory abnormality that may increase the risk associated with study participation or study treatment administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the patient inappropriate for entry into this study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Avelumab
Generic name:	Anti-PD-L1
Product type:	Medicine
Brand name:	diphenhydramine
Generic name:	anti-histamine h2 blocker
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-03-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-06-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-07-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-07-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-08-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-02-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	07-03-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-07-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-11-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-12-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-09-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	19-03-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-04-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-05-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-06-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-07-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-08-2021

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-10-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-10-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2015-003262-86-NL
ClinicalTrials.gov	NCT02603432
CCMO	NL56203.056.16