AN OPEN LABEL, SINGLE ARM, MULTICENTER, SAFETY STUDY OF ATEZOLIZUMAB IN LOCALLY ADVANCED OR METASTATIC UROTHELIAL OR NON-UROTHELIAL CARCINOMA OF THE URINARY TRACT

Published: 09-01-2017
Last updated: 12-04-2024

This study is being conducted to evaluate the safety of atezolizumab as second-line treatment for locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract. The study includes evaluation of the efficacy of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50098

Source
ToetsingOnline

Brief title
MO29983 / SAUL

Condition

- Other condition

Synonym
cancer, Urothelial and non-urothelial cancer

Health condition

urotheel en non-urotheel kanker van de urinewegen

Research involving
Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche

Intervention

Keyword: Atezolizumab, Safety Study, Single arm, Urothelial or non-urothelial carcinoma of the urinary tract

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the safety of atezolizumab

based on the following endpoints:

* Nature, severity, duration, frequency and timing of adverse events (AEs)

* Changes in vital signs, physical findings, and clinical laboratory results

during and following atezolizumab administration

Safety assessments will consist of monitoring and recording adverse events,

including SAEs and adverse events of special interest, performing

protocol-specified safety laboratory assessments, measuring protocol-specified

vital signs, and conducting other protocol-specified tests that are deemed

critical to the safety evaluation of the study.

Secondary outcome

The secondary objectives of the study include evaluation of the efficacy of

atezolizumab based on the following disease response endpoints:

* Overall survival (OS)

* Progression-free survival (PFS

* Overall response rate (ORR), defined as the proportion of patients with a

best overall response of either complete response (CR) or partial response

(PR).

* Disease control rate (DCR)

* Duration of response (DoR)

* Evaluation of efficacy of atezolizumab according to the following

patient-reported outcomes

Study description

Background summary

Atezolizumab is a humanized immunoglobulin G, subclass 1 (IgG1) monoclonal antibody consisting of two heavy chains (448 amino acids) and two light chains (214 amino acids). Atezolizumab was engineered to eliminate the crystallizable fragment (Fc)-effector function via a single amino acid substitution that results in a non-glycosylated heavy chain that has minimal binding to Fc receptors and prevents Fc-effector function at expected concentrations in humans. Atezolizumab targets human programmed death-ligand 1 (PD-L1) and inhibits its interaction with its receptor, programmed cell death protein 1 (PD-1). Atezolizumab also blocks the binding of PD-L1 to B7.1, an interaction that is reported to provide additional inhibitory signals to T cells (Butte et al. 2007). Therapeutic blockade of PD-L1 by atezolizumab is expected to enhance the magnitude and quality of tumor-specific T-cell responses, resulting in improved anti-tumor activity. Consequently, atezolizumab is being investigated as a potential therapy against solid tumors and hematologic malignancies in humans.

Study objective

This study is being conducted to evaluate the safety of atezolizumab as second-line treatment for locally advanced or metastatic urothelial or

non-urothelial carcinoma of the urinary tract. The study includes evaluation of the efficacy of atezolizumab and potential tumor biomarkers associated with atezolizumab.

Study design

Study MO29983 is an open label, single-arm, multicenter study of the safety of atezolizumab as second-line treatment for patients with locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract.

Intervention

Atezolizumab 1200 mg, every 3 weeks, intravenously

Study burden and risks

The subject may experience side effects of the study drug or procedures used in this study. Side effects can range from mild to severe and can vary from person to person. Everyone who participates in the survey will be closely monitored for any side effects. Roche, the study doctor and other doctors, however, do not know all the side effects that could occur. The research doctors can give participants medication to help reduce side effects and may need to stop the subject temporarily or permanently using atezolizumab. Many side effects disappear soon after the patient stops what causes the side effects. In some cases, side effects can be severe, long persist or never disappear. There is also a very small risk of death. The patient should talk to the study doctor about any side effects that may occur during participation in the study.

Adverse reactions known to be associated with atezolizumab
Of the side effects described in this section is known to be associated with atezolizumab.

Adverse reactions known to be associated with atezolizumab
Common (occurs in more than 10% of patients)
* Fatigue
* Joint pain (arthralgia)
* Lack of energy (asthenia)
* Back Pain
* Decreased appetite
* Diarrhea
* Shortness of breath (dyspnea)
* Pain in the stomach (abdominal pain)
* Headache
* Itchy skin
* Nausea
* Fever

* Rash
* Vomiting
Uncommon (affects
1% *10% of patients)
* Chills
* Difficulty in swallowing (dysphagia)
* Increase in liver enzymes, which may indicate inflammation of the liver
* A high concentration of sugar in the blood (hyperglycaemia)
* Allergic reaction or intolerance to medication (hypersensitivity)
* Diminished concentration of potassium in the blood (hypokalemia)
* Reduced sodium levels in the blood (hyponatraemia)
* Low blood pressure (hypotension)
* Under active thyroid (hypothyroidism)
* Decreased supply of oxygen in the body, resulting in shortness of breath (hypoxia)
* Flu-like symptoms
* Infusion-related reactions
* Muscle and bone pain (musculoskeletal pain)
* Nerve damage, possibly resulting in numbness, pain and / or loss of motor function (peripheral neuropathy)
* Inflammation of the lungs (pneumonitis)
* Low number of platelets in the blood, giving you a greater chance of bruising or bleeding (thrombocytopenia)

Rare but potentially serious side effects (occurring in less than 1% of patients)
* Decreased production of hormones by the adrenal gland (adrenal)
* Diabetes
* Overactive thyroid (hyperthyroidism)
* Inflammation of the liver (hepatitis)
* Inflammation of the colon (colitis)
* Nerve damage which can cause muscle weakness and / or paralysis (Guillain-Barré syndrome)
* Inflammation of the brains and the membrane around the brains and spinal cord (meningo-encephalitis)
* Nerve damage resulting in muscle weakness (myasthenic syndrome / myasthenia gravis)
* Inflammation of the pancreas (pancreatitis)
* Increased concentration pancreatic enzymes, which may indicate inflammation of the pancreas (increased levels of amylase and lipase)
* Severely elevated concentrations of sugar and acids in the blood or urine (diabetic ketoacidosis)

At the side effects known to be associated with atezolizumab like Roche and research your doctors you to be extra careful about the following:
* Inflammation of the colon (colitis); possible symptoms include diarrhea, bloody stools and abdominal pain.

* Inflammation of the thyroid gland (hypothyroidism, hyperthyroidism); possible symptoms include headache, fatigue, weight loss, weight gain, mood changes, hair loss and constipation.
* Inflammation of the adrenal gland (adrenal fatigue); possible symptoms include dizziness, irritability, fainting, low blood pressure, darkening of the skin, and craving for salty foods.
* Inflammation of the liver (hepatitis); possible symptoms include yellowing of the skin, pain in the abdomen, nausea, vomiting, itching, fatigue, bleeding or bruising under the skin, and dark urine.
* Inflammation of the brains and the membrane around the brains and spinal cord (meningo-encephalitis); possible symptoms include a stiff neck, headache, fever, chills, vomiting, seizures, irritability and sensitivity of the eyes to light.
* Nerve damage that results in muscle weakness (myasthenic syndrome / myasthenia gravis); possible symptoms are weakness in the arm and leg muscles, double vision and difficulty speaking and chewing.
* Nerve damage which can cause muscle weakness and / or paralysis (Guillain-Barré syndrome); possible symptoms include tingling in the fingers and toes, fatigue, and difficulty walking.
* Inflammation of the lungs (pneumonitis); possible symptoms are newly occurring or worsening cough, shortness of breath and chest pain.
* Reactions associated with infusion (side effects that occur during infusion or within 1 day of infusion); Symptoms include fever, chills, shortness of breath, and suddenly red in the face, neck / throat or chest.
* Inflammation of the pancreas (pancreatitis); symptoms may include abdominal pain, nausea, vomiting and fever.
* disorder with high concentration of sugar in the blood (diabetes mellitus); possible symptoms include increased thirst, increased hunger, frequent

Allergic reactions

At atezolizumab may experience allergic reactions. These usually occur for while it is given into your vein or shortly after administration. The symptoms can include nausea, vomiting, skin reactions (hives or rash), breathing difficulties or low blood pressure. These reactions can be mild or severe and may result in death or permanent disability. If you have any of these symptoms, your study doctor will interrupt the administration of atezolizumab into your vein or even stop. Your study doctor can also give you medicines to treat these symptoms.

Adverse reactions possibly related to atezolizumab
The following side effects may be related to atezolizumab:
* There is a chance that your immune system specific antibodies (proteins made in the body that respond to a foreign substance) develops to this research tool. If you develop these specific antibodies would may affect the ability of your body to react in the future atezolizumab.
* Potential to cause harm to the developing fetus

* Eye inflammation; possible symptoms include eye pain and redness, vision problems or blurry vision (uveitis).
* Inflammation of the kidney; possible symptoms include frequent urination, pelvic pain, and swelling of the body which can result in failure of the kidneys (nephritis).
* Inflammation or damage to the muscles; possible symptoms include muscle pain and weakness, urine with a dark brown or red color, and nausea or vomiting (myositis, myopathy including rhabdomyolysis).

Systemic immune activation
In rare situations, when atezolizumab is combined with another medicine that increases the immune response of your body (an immune modulating drug), can occur more than normal (excessive) immune response. Like other immune-mediated diseases, can cause excessive immune activation, systemic side effects associated with severe inflammation and / or generalized infection (sepsis). Here, various organs in your body (such as your liver, kidneys, lungs and bone marrow) become involved, causing a serious condition that can lead to hospitalization, life-threatening conditions or even death. Possible symptoms of systemic immune activation, are a very low blood pressure that does not respond to standard treatment * including administration of fluids via the veins (intravenous fluid administration), a high temperature (a temperature higher than 38.5 *C), cough, severe shortness of breath (dyspnea), which oxygen therapy and / or mechanical support (intubation) is required, severe dizziness, confusion, weakness, reduced urination with loss of kidney function (renal failure), significantly increased liver enzymes (liver failure), very low numbers of blood cells and / or bleeding in the organs.

If you warn one or get more of these symptoms you should contact your doctor immediately as you may need immediate treatment and should be hospitalized. Your study doctor may give you medicines to treat these symptoms.

Other medications

If you need a live attenuated vaccine, you should get at least 4 weeks before you are treated with atezolizumab. You must agree to not to live attenuated vaccines (eg. FluMist®) to be given during treatment or within 5 months after the last dose atezolizumab. If you know you'll need a vaccination during the investigation, you should tell your doctor.
Atezolizumab may have a number of side effects, the side effects caused by other drugs which also stimulate the immune system, may overlap. It can be dangerous to use atezolizumab together with such other drugs. It is important to tell your doctor if you have used for the last medication that stimulates the immune system. It is also important that you not use other medicines in the 10 weeks after your last dose atezolizumab that may affect your immune system (immunomodulatory drugs).
It is not known how long after discontinuation of study drug will / will persist side effect (s) of study drug.

Potential risks and inconveniences associated with blood

During this study, small amounts of blood drawn from a vein, and used for testing on the basis of which your research doctors can see how it goes with you. Blood collection can cause pain where the needle is inserted, and there is a small risk of bruising or infection at the puncture site. Some people get dizzy, get an upset stomach or faint when their blood is collected.
Potential risks and inconveniences associated with CT scans
CT scans are special X-ray tests that are used to examine the internal organs and bones of the body, and they are required to measure your response to this treatment. You'd probably get these scans if you would participate in this scientific research, as your doctor should your illness eye should take.
You will from the start of study treatment for 54 weeks, approximately every 9 weeks to be exposed to radiation from CT scans and then every 12 weeks until disease progression or termination of the investigation (whichever is first on the agenda). If you do not participate, you can be scanned with a similar frequency or less often (this depends on your cancer center and research your doctor). Through your participation in this study may therefore increase your exposure to radiation from the scans. One possible effect that could occur at doses in connection with this study was a slight increase in the risk of developing cancer later in life. Since the effects of radiation may accumulate over time, it is important to be aware of your radiation exposure in the past. If you are exposed to in the past 12 months by CT scans, X-rays or other means of radiation, inform please the research team. If it is determined that your previous radiation exposure exceeds the applicable guidelines, it is possible that you will not participate in this study.
As part of the CT-scan, it may be necessary to include in a contrast agent via the mouth and / or to have it injected into a vein in order to make visible certain organs and disease locations on the scan. A contrast agent administered via the mouth could lead to side effects such as nausea, constipation, diarrhea and a swollen abdomen. At the place where a needle is inserted to administer contrast material into your vein you may experience pain, ecchymosis, redness and swelling or infection. It is normal to have a warm, flushed sensation when the contrast material is administered. You can get an allergic reaction to the contrast material rashes, hives, shortness of breath, can cause wheezing and itching, and in rare cases, result in your heart stops beating (cardiac arrest). The use of contrast material during these tests would be a normal part of monitoring your response to therapy, even if you would not participate in this scientific research.

Possible risks and discomforts associated with MRI scans

MRI scans are special imaging procedures that are needed to measure your response to this treatment. For most patients, the risks or side effects associated with undergoing MRI scans minimal. An MRI scan will be used no ionizing radiation, as in conventional X-rays. Instead, it will continue to generate images with the aid of a magnetic field and radio signals. Because an

MRI scanner uses strong magnets, you should not undergo MRI if you have any metal implants in your body. People with an artificial heart valve, metal sheet, pen, or other metal objects in their bodies (including hail of shrapnel) are not eligible for MRI scans. The research team will ask questions to make sure you can safely undergo an MRI scan.
There may be some of anxiety and claustrophobia (fear to be in small spaces) in connection with the scanner. Staff at the center use imaging techniques to reduce such feelings in patients. Also can prescribe your research doctor mild tranquilizers or anti-anxiety medicines to help reduce your symptoms. As part of the standard MRI scan there is provided a contrast agent comprising gadolinium is injected into a vein, in order to improve the visibility. The risks associated with the contrast agent include mild nausea, headache, hives, temporary low blood pressure, chest pain, back pain, fever, weakness and seizures. There have been reports of severe and potentially fatal condition called "nephrogenic systemic fibrosis (NSF, a condition in which fibrosis occurs and which can result in kidney failure). This condition has been reported in patients receiving contrast agent based on gadolinium. This disorder is not seen in patients with normal functioning kidneys or slight problems with the kidney function. Before being included in the study, will carry out your research doctor tests to determine if your kidneys are working properly. This is to check that the contrast agent is safe for you.

Potential risks and discomfort associated with biopsies

The risks associated with biopsies include pain, redness, swelling, excessive bleeding, bruising or fluid drainage in the slot, abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site.

Risks related to reproduction

If you are pregnant, or if you are currently breastfeeding, you should not participate in this study because you or your child may be exposed when participating to an unknown risk.
If you are a woman who may become pregnant, you should have a blood test showing that you are not pregnant before you can participate in this study. Also will urge you did a pregnancy test blood or urine regularly during the investigation. As a result of a blood or urine test is positive, you will not receive doses atezolizumab more.
If you become pregnant, you must agree to abstain from sexual intercourse or use of contraceptive methods considered effective by your study doctor. You must use this during this investigation and atezolizumab after your last dose for 5 months. Ask your doctor what research methods of contraception should be used. Also, you should not breastfeed for 5 months after your last dose atezolizumab.
Tell it directly to your study doctor if you suspect that you have become pregnant during the study or within 5 months after your last dose atezolizumab.

The study doctor or research staff will inform you about the possible risks to your unborn child and the options available to you.

Contacts

Public
Roche Nederland B.V.

Beneluxlaan 2a Beneluxlaan 2a
Woerden 3446 GR
NL
Scientific
Roche Nederland B.V.

Beneluxlaan 2a Beneluxlaan 2a
Woerden 3446 GR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 18 years;- Histologically documented locally advanced (tumor (T) 4b, any node (N); or any T, N 2*3) or metastatic (M1, Stage IV) urothelial or non-urothelial carcinoma of the urinary tract;- Patients with measurable and non-measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 are allowed;- Must have received one prior combination chemotherapy regimen (e.g., methotrexate, vinblastine, doxorubicin, and cisplatin [MVAC], gemcitabine and cisplatin [GC], etc.) for inoperable, locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract;- Representative formalin-fixed paraffin-embedded (FFPE) tumor specimen block available for submission;-

Eastern cooperative oncology group (ECOG) performance status 0, 1 or 2;- Life expectancy >< = 12 weeks;- Adequate hematologic and end-organ function, defined by the following laboratory results obtained within 2 weeks prior to the first study treatment;- Patients with treated, asymptomatic central nervous system (CNS) metastases are eligible (Note: Patients on stable doses of anticonvulsants or on prednisone doses [or dose equivalents] of <<= 20 milligram/day are allowed);- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 5 months after the last dose of atezolizumab

Exclusion criteria

- Treatment with more than three prior lines of systemic therapy for inoperable, locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract;- Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 4 weeks prior to study treatment initiation;- Treatment with chemotherapy within 2 weeks prior to study treatment initiation;- Treatment with radiotherapy ongoing at the time of study entry (for CNS-directed radiotherapy);- Pregnant or lactating, or intending to become pregnant during the study;- Evidence of significant uncontrolled concomitant disease that could affect compliance with the protocol, including significant liver disease (such as cirrhosis, uncontrolled major seizure disorder, or superior vena cava syndrome);- Significant cardiovascular disease, such as New York Heart Association cardiac disease >= Class III, myocardial infarction within 3 months, unstable arrhythmias, or unstable angina;- Significant renal disorder requiring dialysis or indication for renal transplant;- Signs or symptoms of severe infection within 2 weeks prior to initiation of study treatment, including but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia;- Major surgical procedure within 4 weeks prior to study treatment initiation or anticipation of need for a major surgical procedure during the course of the study other than for diagnosis;- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins;- Known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation;- History of autoimmune disease are allowed if controlled and on stable treatment (i.e., same treatment, same dose) for the last 12 weeks;- Prior allogeneic stem cell or solid organ transplantation;- History of idiopathic pulmonary fibrosis (including pneumonitis, drug-induced pneumonitis, organizing pneumonia (i.e. bronchiolitis obliterans, cryptogenic organizing pneumonia), or evidence of active pneumonitis on screening chest computed tomography (CT) scan;- Patients with active hepatitis B (defined as having a positive hepatitis B surface antigen [HBsAg] test at screening) or hepatitis C;- Active tuberculosis;- Administration of a live, attenuated vaccine within 4 weeks prior to study treatment initiation;- Prior treatment with cluster of differentiation (CD) 137 agonists or immune checkpoint blockade therapies, including anti* cytotoxic T lymphocyte-associated (CTLA)-4, anti* programmed cell death protein 1 (PD-1), and anti* programmed death-ligand 1 (PD-L1) therapeutic antibodies;- Treatment with systemic immunostimulatory agents (including, but not limited to, interferons or interleukin-2) within 4 weeks or five half-lives of the drug, whichever is shorter, prior to initiation of study treatment;- Specifically for patients

without autoimmune disease, treatment with systemic corticosteroids or other systemic immunosuppressive medications within 2 weeks prior to study treatment initiation or anticipated requirement for systemic immunosuppressive medications during the study treatment period. Note: For patients with autoimmune disease, immunosuppressive medications are permitted if the patient has controlled autoimmune disease and stable treatment (i.e., same treatment, same dose) for the previous 12 weeks

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tecentriq
Generic name:	Atezolizumab

Ethics review

Approved WMO

Date:	09-01-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	13-03-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-08-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-08-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-10-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-12-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-04-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-04-2018

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-05-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-06-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-06-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-02-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-02-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	11-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-02-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-03-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-04-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-08-2022
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-11-2022
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	EUCTR2016-002625-11-NL
ClinicalTrials.gov	NCT02928406
CCMO	NL59511.056.16