# AN OPEN-LABEL, FIXED-SEQUENCE, ASCENDING-DOSE, FIRST-IN-HUMAN STUDY TO ASSESS THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, AND EFFICACY OF INTRAVENOUS INFUSIONS OF ATB200 CO-ADMINISTERED WITH ORAL AT2221 IN ADULT SUBJECTS WITH POMPE DISEASE

Published: 25-04-2016
Last updated: 20-04-2024

To evaluate the safety, tolerability, PK, PD and efficacy of intravenous (IV) ATB200 alone and when co-administered with oral AT2221.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Congenital and hereditary disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50710

**Source**
ToetsingOnline

**Brief title**
ATB200-02

### Condition

- Congenital and hereditary disorders NEC

**Synonym**

hereditary muscle disease, neuromuscular disorder

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Amicus Therapeutics, Inc.
**Source(s) of monetary or material Support:** Amicus Pharmaceuticals;Inc.

## Intervention

**Keyword:** First-in-human study, Open-label, Pompe Disease

## Outcome measures

### Primary outcome

* To evaluate the safety and tolerability of single-ascending doses of

intravenously (IV) infused ATB200

* To evaluate the safety and tolerability of single-ascending doses of IV

infused ATB200 as a fixed dose, co-administered with ascending oral doses of

AT2221

* To characterize the pharmacokinetics (PK) of single-ascending doses of IV

infused ATB200

* To characterize the single- and multiple dose PK of IV infused 20 mg/kg

ATB200 when co-administered with oral 130 mg or 260 mg AT2221

* To characterize the PK of single- and multiple-oral doses of 130 mg or 260 mg

AT2221 when co-administered with IV infused ATB200

### Secondary outcome

* To evaluate the long-term efficacy of 20 mg/kg of IV infused ATB200 as a

fixed dose co-administered with oral 260 mg AT2221 in all subjects from Stage 3

* To evaluate the long-term safety and tolerability of 20 mg/kg of IV infused

ATB200 as a fixed dose co-administered with oral 260 mg AT2221 in all subjects from Stage 3

* To characterize single- and multiple-dose PK of plasma rhGAA activity and total rhGAA protein following IV infused 20 mg/kg ATB200 as a fixed dose co-administered with oral 260 mg AT2221 in enzyme replacement therapy (ERT)-naïve subjects

* To characterize the single- and multiple-dose PK of plasma AT2221 following 20 mg/kg of IV infused ATB200 co-administered with oral 260 mg AT2221 in ERT-naïve subjects

# Study description

**Background summary**

Management of Pompe disease includes enzyme replacement therapy (ERT) with recombinant human *-glucosidase (rhGAA), cardiopulmonary and gastrointestinal support, musculoskeletal and functional rehabilitation, and dietary therapy. Alglucosidase alfa is the only ERT approved for the treatment of Pompe disease. In subjects with IOPD (infantile-onset Pompe disease), treatment with alglucosidase alfa has been shown to significantly improve survival compared to historical controls (Myozyme Package Insert 2010). In LOPD (late-onset Pompe disease), alglucosidase alfa has been shown to have a statistically significant, albeit modest, effect on the 6-Minute Walk Test (6MWT) and forced vital capacity (FVC) compared to placebo (Myozyme Package Insert 2010). However, the majority of subjects either remain stable or continue to deteriorate while on alglucosidase alfa. The reason for the apparent sub-optimal effect of ERT is unclear, but could be partly due to the poor tissue targeting of the current ERT, development of anti-rhGAA neutralizing antibodies, or the progressive nature of underlying muscle pathology. The effect of alglucosidase alfa is less clear for subjects who are already nonambulatory or receiving ventilatory support. The US product label includes a black box warning with information on the potential risk of hypersensitivity reaction. Life-threatening anaphylactic reactions, including anaphylactic shock, have been observed in subjects treated with alglucosidase alfa.

This study aims to evaluate the effect of a better targeted rhGAA (ATB200) co-administered with a chaperone (AT2221) that has been shown to increase the stability of ERT resulting in the delivery of more active enzyme to the target tissues. Additionally, the study aims to evaluate
safety, tolerability, pharmacodynamics (PD), and immunogenicity of ATB200 co-administered with AT2221 in nonambulatory adult subjects with Pompe disease, a significant population that is yet to be studied.

**Study objective**

To evaluate the safety, tolerability, PK, PD and efficacy of intravenous (IV) ATB200 alone and when co-administered with oral AT2221.

**Study design**

This is an open-label, fixed-sequence, single- and multiple-ascending dose, first-in-human (FIH) study to evaluate the safety, tolerability, PK, PD and efficacy of intravenous (IV) ATB200 alone and when co-administered with oral AT2221. The study will be conducted in 4 stages.

Approximately ten to 12 ERT-experienced (alglucosidase alfa) ambulatory subjects (Cohort 1 ) will be enrolled in Stages 1 and 2.
In Stage 1, safety, tolerability, and PK will be evaluated following sequential single-ascending doses of 5 mg/kg, 10 mg/kg, and 20 mg/kg of IV infused ATB200 administered 2 weeks apart. In Stage 2, safety, tolerability, and PK will be evaluated following single- and multiple-ascending dose combinations: 20 mg/kg of IV infused ATB200 co--administered with 130 mg of AT2221 administered orally every 14 days (±3 days) for 3 doses, followed by 20 mg/kg of IV infused ATB200 co-administered with 260 mg of AT2221 administered orally for 3 doses (Table 1). ERT-experienced ambulatory subjects who complete Stages 1 and 2 will enter into a long-term extension stage of the study, hereinafter referred to as Stage 3, and will continue to be assessed for safety, tolerability, and efficacy of extended treatment with 20 mg/kg of IV ATB200 co-administered with 260 mg of AT2221 administered orally. In addition, disease-relevant functional assessments will be performed at regular (6-month) intervals.

In Stage 3, approximately, 12 to 18 additional subjects will enroll, of whom approximately 4 to 6 ERT-experienced non-ambulatory (Cohort 2), 5 ERT-naïve ambulatory subjects (Cohort 3) , and approximately 6 tot 8 will be ERT-experienced ambulatory subjects who have completed at least 7 years of ERT (Cohort 4). These subjects will be treated with 20 mg/kg of IV infused ATB200 co-administered with 260 mg of AT2221 administered orally every 2 weeks and evaluated for safety, tolerability, PD, and efficacy. Duration of Stage 3 will be 2 years.

Stage 4 treatment period will begin at the end of Stage 3 and continue as an

open label extension until subject withdrawal, regulatory approval or marketing authorization and/or commercialization in the participating subject*s country, or study termination by the sponsor, Amicus Therapeutics, Inc. (Amicus).

ERT-naïve subjects will also undergo blood sample collection for single- and multiple-dose PK assessments in the same manner as in Stage 2, Period 5 for ERT-experienced ambulatory subjects. Based on having previous exposure to ERT, PK assessments are expected to be similar in ERT-experienced nonambulatory and ERT-experienced ambulatory subjects. In addition, the intensive PK sampling in this study is likely to present an undue burden to nonambulatory subjects. For these reasons, no PK assessments will be conducted in ERT-experienced nonambulatory subjects.

ERT-experienced ambulatory subjects are defined as adults diagnosed with Pompe disease who have been on ERT for 2 to 6 years (Cohort 1) or * 7 years (Cohort 4) prior to enrollment, and who are able to walk at least 200 meters in the 6-minute walking test (6MWT).

ERT-experienced non-ambulatory subjects (Cohort 2), are defined as adults diagnosed with Pompe disease who are wheelchair bound, unable to walk unassisted, and have been on ERT for *2 years prior to enrollment.

ERT-naïve ambulatory subjects (Cohort 3), are defined as adults with Pompe disease who have never received treatment with ERT and who are able to walk at least 200 meters in the 6MWT.

**Intervention**

See Study Design

**Study burden and risks**

As with any investigational new drug or research study procedure, there are risks and discomforts. The risks and discomforts of ATB200 are described in the Patient Information and Informed Consent Form in section 6.

Other risks associated with study procedures and pregnancy are:
Blood Sampling: You will provide blood samples as part of the study procedures. When blood samples are taken, a needle is put into a vein in your arm. The amount of blood taken will not be more than what is safe and recommended for someone your size.
Risks associated with drawing your blood may include:
* Redness, swelling, pain or discomfort at the site of the needle stick
* Bruising at the site of the needle stick
* Some people may experience lightheadedness, dizziness and/or fainting
* Although rare, infection may occur

Electrocardiogram (ECG): An electrocardiogram measures the electrical activity of your heart. Stickers will be attached to your chest, arms and legs that are connected with wires to a machine. Most people do not experience any discomfort during the procedure. You may sometimes get mild skin irritation caused by these stickers on your skin.

Genetic Testing (gene mutations): In this study, genetic testing will be done to find out what mutation or mutations you have that causes your Pompe disease, if this information is not already known. Genetic testing can provide information about how health or illness is passed on to you by your parents or from you to your children. Having this knowledge may affect your emotional wellbeing. You might feel differently about yourself and your life if you learned that you and your children were at increased risk of having a disease, especially if there were no treatment.

Because of the emotional risk, some people who participate in research studies do not want to know the results of genetic testing. It is our policy to not disclose the results of genetic testing unless it has direct medical or reproductive implications for you or your family. You may choose to receive your information or you may choose not to receive your information. It is your decision. Whether you choose to receive the information or not, by agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your medical records. For further information on those rights, you can contact the study doctor.

Risks of Pregnancy and Need for Birth Control:
The risks to any baby that may be conceived by you or your partner while you are taking this drug are unknown. Results of a study in pregnant rabbits that looked at their offspring after doses that were greater then 10 times the human dose showed development effects on the heart of the offspring. Therefore, women in the study who can become pregnant (that is, ovulating, pre-menopausal, not surgically sterile) and all men in the study will be required to be sexually abstinent or use a highly effective (double barrier) method of contraceptive (birth control) regimen throughout the study and for 90 days following the last doses of study drugs, as outlined below.
Acceptable methods for male participants at time of 1st dose of ATB200 and AT2221 and until 90 days after the last dose of protocol defined study medication are:
* condoms with spermicide
* condoms in conjunction with partners* use of diaphragm, or oral, injected, or implanted hormonal methods of contraception
* surgical sterilization of patient at least 26 weeks before the Screening Visit (vasectomy)
Acceptable methods for female participants at time of 1st dose of ATB200 and AT2221 and until 90 days after the last dose of protocol defined study medication are:
* Total abstinence: When this is in line with the preferred and usual lifestyle

of the subject. Periodic abstinence (eg, calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception
* surgical sterilization of patient at least 26 weeks before the Screening Visit (includes hysterectomy or bilateral tubal ligation, oophorectomy, or salpingectomy)
* male partner(s) sterilization
* Use a combination of two
a) Placement of a non-hormonal intrauterine device (IUD) or non-hormonal intrauterine system for at least 12 weeks before the Screening Visit
b) Barrier method of contraception: Condom or diaphragm (cervical vault cap) with spermicidal foam/gel/ film/cream/vaginal suppository (not applicable in Australia)
c) Hormonal contraception methods (oral, injected or implanted)

If you or your partner becomes pregnant during this study, please notify the study doctor immediately.

For an overview of the study procedures please consult Annex I in the ICF.
The intensive PK sampling in this study is likely to present an undue burden to nonambulatory subjects. For these reasons, no PK assessments will be conducted in ERT-experienced nonambulatory subjects.

## Contacts

**Public**
Amicus Therapeutics, Inc.

1 Cedar Brook Drive NA
NA NA
US
**Scientific**
Amicus Therapeutics, Inc.

1 Cedar Brook Drive NA
NA NA
US

## Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Cohort 1
1. Male and female subjects between 18 and 65 years of age, inclusive
2. Subject must provide signed informed consent prior to any study-related procedures
3. Subjects of childbearing potential must agree to use medically accepted methods of
contraception during the study and for 90 days after last co-administration of ATB200 and AT2221
4. Subject has a diagnosis of Pompe disease based on documented deficiency of GAA
enzyme activity or by GAA genotyping
5. Subject has received ERT with alglucosidase alfa (Myozyme/Lumizyme) for the previous 2 to 6 years, inclusive
6. Subject is currently receiving alglucosidase alfa (Myozyme/Lumizyme) at a frequency of once every other
week
7. Subject has received and completed the last two infusions without a drug-related
adverse event resulting in dose interruption
8. Subject must be able to walk between 200 and 500 meters on the 6MWT
9. Upright forced vital capacity (FVC) must be 30% to 80% of predicted normal value, Cohort 2
10. Male and female subjects between 18 and 65 years of age, inclusive
11. Subject must provide signed informed consent prior to any study-related procedures
12. Subjects of childbearing potential must agree to use medically accepted methods of
contraception during the study and for 90 days after last co-administration of ATB200
and AT2221
13. Subject has a diagnosis of Pompe disease based on documented deficiency of GAA

enzyme activity or by GAA genotyping
14. Subject has received ERT with alglucosidase alfa (Myozyme/Lumizyme) for *2 years
15. Subject is currently receiving alglucosidase alfa (Myozyme/Lumizyme) at a regular or set frequency
16. Subject has received and completed the last two infusions without a drug-related adverse
event resulting in dose interruption.
17. Subject must be wheelchair-bound and unable to walk unassisted, Cohort 3
18. Male and female subjects between 18 and 65 years of age, inclusive
19. Subject must provide signed informed consent prior to any study-related procedures
20. Subjects of childbearing potential must agree to use medically accepted methods of
contraception during the study and for 90 days after last co-administration of ATB200
and AT2221
21. Subject has a diagnosis of Pompe disease based on documented deficiency of GAA
enzyme activity or by GAA genotyping
22. Subject must be able to walk between 200 to 500 meters on the 6MWT
23. Upright FVC must be 30% to 80% of predicted normal value, Cohort 4
24. Male and female subjects between 18 and 75 years of age, inclusive
25. Subject must provide signed informed consent prior to any study-related procedures
26. Subject has documented 6MWT on three separate occasions, each at least six months apart with at least two values in the past three years
27. Subjects of childbearing potential must agree to use medically accepted methods of contraception during the study and for 90 days after last co-administration of ATB200 and AT2221
28. Subject has a diagnosis of Pompe disease based on documented deficiency of GAA enzyme activity or by GAA genotyping
29. Subject has received ERT for the previous * 7 years
30. Subject is currently receiving alglucosidase alfa (Myozyme/Lumizyme) at a frequency of once every other week
31. Subject has received and completed the last 2 infusions without a drug-related AE resulting in dose interruption
32. Subject must be able to walk between 75 and 600 meters on the 6MWT
33. Upright FVC must be 85% of predicted normal value

## Exclusion criteria

Cohort 1
1. Subject has received any investigational therapy including adjunctive therapy for Pompe disease, other than alglucosidase alfa within 30 days or 5

half-lives of the therapy or treatment, whichever is longer, prior to the Baseline Visit, or anticipates doing so during the study
2. Subject has received treatment with prohibited medications (see protocol section 8.7) within
30 days of the Baseline Visit
3. Subject, if female, is pregnant or breastfeeding at screening
4. Subject, whether male or female, is planning to conceive a child during the study
5. Subject requires invasive ventilatory support
6. Subject uses noninvasive ventilatory support *6 hours a day while awake
7. Subject has a medical or any other extenuating condition or circumstance that may, in
the opinion of the investigator or the Medical Monitor, pose an undue safety risk to the subject or
compromise his/her ability to comply with protocol requirements
8. Subject has a history of anaphylaxis to alglucosidase alfa
9. Subject has a history of high sustained anti-rhGAA antibodies (see Section 10.4)
10. Subject has a history of allergy or sensitivity to miglustat or other iminosugars
11. Subjects with active systemic autoimmune disease such as lupus, scleroderma, or rheumatoid arthritis. All subjects with autoimmune disease must be discussed with Amicus Medical Monitor
12. Subjects with active bronchial asthma. All subjects with bronchial asthma must be discussed with the Amicus Medical Monitor, Cohort 2
13. Subject has received any investigational therapy including adjunctive therapy for Pompe disease, other than alglucosidase alfa within 30 days or 5 half-lives of the therapy or treatment, whichever is longer, prior to the Baseline Visit, or anticipates to do so during the study
14. Subject has received treatment with prohibited medications (see protocol section 8.7) within
30 days of the Baseline Visit
15. Subject, if female, is pregnant or breastfeeding at screening
16. Subject, whether male or female, is planning to conceive a child during the study
17. Subject has a medical or any other extenuating condition or circumstance that may, in
the opinion of the investigator or the Medical Monitor, pose an undue safety risk to the subject or compromise his/her ability to comply with protocol requirements
18. Subject has a history of anaphylaxis to alglucosidase alfa
19. Subject has a history of high sustained anti-rhGAA antibodies (see Section 10.4)
20. Subjects has a history of allergy or sensitivity to miglustat or other iminosugars
21. Subjects with active systemic autoimmune disease such as lupus, scleroderma, or rheumatoid arthritis. All subjects with autoimmune disease must

be discussed with the Amicus Medical Monitor
22. Subjects with active bronchial asthma. All subjects with bronchial asthma must be discussed with the Amicus Medical Monitor, Cohort 3
23. Subject has received any enzyme replacement therapy, including alglucosidase alfa at any time, or any investigational therapy for Pompe disease within 30 days or 5 half-lives of the therapy or treatment, whichever is longer, prior to the Baseline Visit, or anticipates doing so during the study
24. Subject has received treatment with prohibited medications within 30 days of the Baseline Visit
25. Subject, if female, is pregnant or breastfeeding at screening
26. Subject, whether male or female, is planning to conceive a child during the study
27. Subject requires invasive ventilatory support
28. Subject uses noninvasive ventilatory support * 6 hours a day while awake
29. Subject has a medical or any other extenuating condition or circumstance that may, in the
opinion of the investigator or the Medical Monitor, pose an undue safety risk to the subject or compromise his/her ability to comply with protocol requirements
30. Subject has a history of allergy or sensitivity to miglustat or other iminosugars
31. Subjects with active systemic autoimmune disease such as lupus, scleroderma, or rheumatoid arthritis. All subjects with autoimmune disease must be discussed with the Amicus Medical Monitor
32. Subjects with active bronchial asthma. All subjects with bronchial asthma must be discussed with the Amicus Medical Monitor, Cohort 4
33. Subject has received any investigational therapy including adjunctive therapy for Pompe disease, other than alglucosidase alfa within 30 days or 5 half-lives of the therapy or treatment, whichever is longer, prior to the Baseline Visit, or anticipates doing so during the study
34. Subject has received treatment with prohibited medications within 30 days of the Baseline Visit
35. Subject, if female, is pregnant or breastfeeding at screening
36. Subject, whether male or female, is planning to conceive a child during the study
37. Subject requires invasive ventilatory support
38. Subject uses noninvasive ventilatory support * 6 hours a day while awake
39. Subject has a medical or any other extenuating condition or circumstance that may, in the opinion of the investigator or the Medical Monitor, pose an undue safety risk to the subject or compromise his/her ability to comply with protocol requirements
40. Subject has a history of anaphylaxis to alglucosidase alfa
41. Subject has a history of high sustained anti-rhGAA antibodies
42. Subject has a history of allergy or sensitivity to miglustat or other iminosugars
43. Subjects with active systemic autoimmune disease such as lupus, scleroderma, or rheumatoid arthritis; all subjects with autoimmune disease must

be discussed with the Amicus Medical Monitor
44. Subjects with active bronchial asthma; all subjects with bronchial asthma must be discussed with the Amicus Medical Monitor

# Study design

## Design

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|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-11-2016 |
| Enrollment: | 2 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Zavesca |
| Generic name: | miglustat |
| Registration: | Yes - NL outside intended use |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 25-04-2016 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

Approved WMO

| | |
|---|---|
| Date: | 25-07-2016 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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|---|---|
| Approved WMO Date: | 28-10-2016 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

| | |
|---|---|
| Approved WMO Date: | 16-11-2016 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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|---|---|
| Approved WMO Date: | 17-02-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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|---|---|
| Approved WMO Date: | 29-03-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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|---|---|
| Approved WMO Date: | 24-04-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

| | |
|---|---|
| Approved WMO Date: | 30-05-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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|---|---|
| Approved WMO Date: | 27-06-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam |

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|---|---|
| | (Rotterdam) |
| Approved WMO Date: | 26-07-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 24-08-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 14-09-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 13-07-2018 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 02-08-2018 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 19-11-2018 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 10-12-2018 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 11-01-2019 |

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|---|---|
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 05-02-2019 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 24-06-2019 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 21-10-2019 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-04-2020 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 14-08-2020 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | EUCTR2015-004798-34-NL |
| CCMO | NL56558.078.16 |