A phase III randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of PRM-151 in patients with idiopathic pulmonary fibrosis

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The current study is a confirmatory, randomized, double-blind, placebo-controlled, Phase III clinical trial to assess the efficacy and safety of PRM-151 in patients with IPF with or without concurrent treatment with pirfenidone or nintedanib.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON52256

Source
ToetsingOnline

Brief title
WA42293 (PRM-151-303)/STARSCAPE

Condition

- Pulmonary vascular disorders

Synonym
cryptogenic fibrosing alveolitis; idiopathic diffuse interstitial pulmonary fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Hoffmann-La Roche
Source(s) of monetary or material Support: F. Hoffmann-La Roche Ltd

Intervention

Keyword: double-blind, phase III, placebo-controlled, PRM-151

Outcome measures

Primary outcome

The primary efficacy objective is to demonstrate superiority of 10 mg/kg PRM-151 plus standard of care treatment as needed (excluding lung transplantation) administered Q4W via IV infusion, over matching placebo plus standard of care treatment as needed (excluding lung transplantation), on lung function on the basis of absolute change in baseline to week 52 in forced vital capacity (FVC (mL))

Secondary outcome

The secondary efficacy objective is to demonstrate superiority of 10 mg/kg PRM-151 plus standard of care treatment as needed (excluding lung transplantation) administered Q4W via IV infusion, over matching placebo plus standard of care treatment as needed (excluding lung transplantation) on the basis of the following endpoints:

* Absolute change from baseline to Week 52 in 6MWD (in meters)

* Absolute change from baseline to Week 52 in FVC% predicted

* Time to disease progression, defined as time to first occurrence of >= 10%

absolute

decline in % predicted FVC, >= 15% relative decline in 6MWD, or death

* Time to first respiratory-related hospitalizations (defined as non-elective

hospitalizations due to any respiratory cause, including acute exacerbations of

IPF,

or suspected acute exacerbations of IPF, as determined by the clinical

Adjudication Committee)

* Change from baseline to Week 52 in University of California, San

Diego*Shortness

of Breath Questionnaire (UCSD-SOBQ)

* Change from baseline to Week 52 in St. George Respiratory Questionnaire (SGRQ)

Total Score

* Time to first acute exacerbation of IPF, or suspected acute exacerbation of

IPF, as

determined by clinical Adjudication Committee

* Change from baseline to Week 52 in carbon monoxide diffusing capacity (DLCO)

* Survival, as measured by all-cause mortality

The exploratory efficacy objective for this study is to evaluate the efficacy

of PRM-151

plus standard of care treatment as needed (excluding lung transplantation)

compared

with matching placebo plus standard of care treatment as needed (excluding lung

transplantation) on the basis of the following endpoints:

* Change from baseline to Week 52 in FVC% predicted, FVC (mL), by concurrent therapy stratum (i.e., with nintedanib treatment vs. with pirfenidone treatment vs.
without pirfenidone or nintedanib treatment)
* Change from baseline to Week 52 in FVC% predicted, FVC (mL), by MUC5B risk allele positive or negative status
* Change from baseline to Week 52 in 6MWD, by concurrent therapy stratum (i.e., with nintedanib treatment vs. with pirfenidone treatment vs. without pirfenidone
or nintedanib treatment)
* Change from baseline to Week 52 in SGRQ Individual Domains (Symptoms, Activity,
and Impacts) Score
* Change from baseline to Week 52 in the 6-minute walk test (6MWT) pre-test to pre-test measurements of Borg dyspnea score, fatigue score, and oxygen saturation
* Change from baseline to Week 52 in the 6MWT pre-test to post-test measurements of Borg dyspnea score, fatigue score, and oxygen saturation
* Change from baseline to Week 52 in the 6MWT post-test to post-test measurements
of Borg dyspnea score, fatigue score, and oxygen saturation
* Change from baseline to Week 52 in quantitative imaging analysis parameters of HRCT scan of the thorax
* Length of hospital stay for respiratory-related hospitalizations, total time

in intensive

care units due to respiratory causes, deaths due to respiratory causes, and

unscheduled outpatient clinic/urgent care/emergency room utilization related to

respiratory events

* A decline or an increase in FVC% predicted of * 5%, * 10%, and * 15% from

baseline to Week 52

* A decline or an increase in FVC in mL of * 100 mL and * 200 mL from baseline

to

Week 52

* A decline or an increase in 6MWD * 5%, * 10%, * 15%, and * 20% from baseline

to

Week 52

* A decline or an increase in 6MWD * 25 m, and 50 m from baseline to Week 52

* Number of acute exacerbations during the 52 weeks

* At least one acute exacerbation during the 52 weeks; as determined by the

clinical Adjudication

Committee

* Survival as measured by IPF-related mortality

* Survival as measured by respiratory-related mortality

* Disease progression defined as: * 10% absolute decline in % predicted FVC;

respiratory hospitalization; or a decline of 50 m in 6MWD

* Disease progression and subsequently start pirfenidone or nintedanib or

switch from

nintedanib to pirfenidone (or vice versa)

* Time to worsening on the UCSD-SOBQ, as indicated by a change in score of 10 points or greater

* Time to worsening on the SGRQ total score, as indicated by a change in score of 7 or greater

* Time to worsening on the SGRQ Activity domain, as indicated by a change in score of 5 or greater

* Time to worsening on the SGRQ Symptom Domain, as indicated by a change in score of 8 or greater

* Time to worsening on the SGRQ Impact Domain, as indicated by a change in score of 7 or greater

* Change in PFT parameters (FVC, 6MWT, or DLCO) from baseline to Week 52 between SARS-CoV2 antibody positive compared with negative patients

* Change in PFT parameters (FVC, 6MWT, or DLCO) from baseline to Week 52 in patients who develop SARS-CoV2 antibodies during treatment (not present at baseline)

Efficacy evaluations will be performed for the primary, secondary, and exploratory efficacy endpoints as detailed in Section 6.5. Exploratory analyses may also be performed for additional measures and subgroups of interest. Details of all such analyses will be provided in the Statistical Analysis Plan (SAP).

The safety objective for this study is to confirm the safety and tolerability of 10 mg/kg of PRM-151 administered Q4W via IV infusion plus standard of care treatment as needed relative to matching placebo plus standard of care treatment as needed in a population of all dosed patients, on the basis of the following endpoints:

* Incidence and severity of adverse events, with severity determined according to the 5-point severity scale (National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 [NCI CTCAE, v.5.0])
* Incidence and severity of IRRs and other adverse events of special interest
* Proportion of patients permanently discontinuing study treatment due to adverse events
* Change from baseline in targeted clinical laboratory test results

Safety analyses may also be performed for subgroups of interest. Details of such analyses will be provided in the SAP.

The pharmacokinetic (PK) objective for this study is to characterize pharmacokinetics of PRM-151 in patients with IPF on the basis of the following:

* Serum concentrations of PRM-151 at specified timepoints

The exploratory PK objectives are to evaluate the potential relationship between drug exposure and the efficacy and safety of PRM-151 on the basis of the following:

* Relationship between PK for PRM-151 and efficacy endpoints
* Relationship between PK for PRM-151 and safety endpoints

The immunogenicity objective for this study is to evaluate the immune response to PRM-151 on the basis of the following:

* Prevalence of ADAs at baseline and incidence of ADAs during the study

The exploratory immunogenicity objective for this study is to evaluate potential effects of ADAs on the basis of the following:

* Relationship between ADA status and efficacy, safety, or PK endpoints

The exploratory biomarker objective for this study is to identify and/or evaluate biomarkers that are predictive of response to PRM-151 (i.e., predictive biomarkers), are early surrogates of efficacy, are associated with progression to a more severe disease state (i.e., prognostic biomarkers), are associated with acquired resistance to PRM-151, are associated with susceptibility to developing adverse events or can lead to

improved

adverse event monitoring or investigation (i.e., safety biomarkers), can

provide evidence

of PRM-151 activity (i.e., pharmacodynamic [PD] biomarkers), or can increase the

knowledge and understanding of disease biology and drug safety, on the basis of

the following:

* Relationship between biomarkers in blood listed in Section 4.5.12 and

efficacy,

safety, PK, immunogenicity, or other biomarker endpoints

The exploratory health status utility objective for this study is to evaluate

health status

utility scores of patients treated with PRM-151 plus standard of care treatment

as

needed on the basis of the following endpoint:

* Change from baseline to Week 52 in EuroQol 5-Dimension, 5-Level Questionnaire

(EQ-5D-5L) index-based, and visual analog scale (VAS) scores

Study description

Background summary

Idiopathic pulmonary fibrosis is a specific form of a chronic-fibrosing interstitial pneumonia limited to the lung. It is a progressive inflammatory lung disease that leads to significant morbidity and mortality. Pentraxin-2 (PTX-2) is a highly conserved endogenous serum protein and a soluble pattern recognition receptor (PRR) of the innate immune system that regulates monocyte activation and differentiation. PRM-151 is a recombinant human pentraxin-2

(rhPTX-2) protein. Of importance, patients with IPF (in comparison to healthy subjects) have both increased fibrocyte numbers in circulation and decreased levels of circulating PTX-2.
Supplementing endogenous PTX-2 levels through intravenous administration of PRM-151 should theoretically increase the regulatory capacity of PTX-2 in circulation and at the site of disease, thereby promoting healing and reducing fibrosis.
Robust nonclinical and clinical data exist to support the investigation of PRM-151 in the treatment of fibrotic diseases. Efficacy and safety of PRM-151 is also being investigated in patients with myelofibrosis in a Phase II study. (see Protocol, 1. Background)

Study objective

The current study is a confirmatory, randomized, double-blind, placebo-controlled, Phase III clinical trial to assess the efficacy and safety of PRM-151 in patients with IPF with or without concurrent treatment with pirfenidone or nintedanib.

Study design

This Phase III, randomized, double-blind, placebo-controlled, pivotal study is designed to confirm the efficacy and safety of PRM-151 in the treatment of patients with IPF during a 52-week period. At the end of this 52-week period, patients will be invited to enroll in an open-label extension (OLE) study (Study WA42294) to receive treatment with PRM-151. Patients who do not enroll in the OLE study will be followed up for an additional 4 weeks (to Week 56, for safety monitoring). The OLE study will provide patients with further study assessments and PRM-151 treatment
on an ongoing basis. However, the OLE study will also consist of a long-term survival cohort, where patients who do not want further study assessments or treatment can enroll (for longterm collection of survival data only). Patients meeting the eligibility criteria for the study will be randomized to PRM-151 10 mg/kg Q4W or placebo. Efficacy will be evaluated through assessment of functional capacity as measured by FVC, 6MWD, other pulmonary function tests (PFTs), and assessment of patients with respiratory events leading to hospitalizations, progression of disease, acute IPF exacerbations.
Patient reported outcomes (PROs) will be assessed using the SGRQ, UCSD-SOBQ, and EQ-5D-5L. Dyspnea, fatigue, and SpO2 will be assessed based on measurements taken during the 6MWT. For patients who require a HRCT scan during the screening period, an additional chest HRCT
scan will be performed at Week 52. Patients who do not require a HRCT scan during the screening period (i.e., they already have a historic HRCT scan of acceptable quality performed within 12 months prior to screening) will not be required to perform a scan at Week 52.Treated patients will be followed until the end of the 52-week study period unless the patient withdraws consent for

follow-up or dies. Patients will be evaluated for study eligibility during a screening period of up to 4 weeks. If any patient is prevented from completing required screening procedures within the 4-week period due to unforeseeable circumstances. Screening can be extended up to a maximum of 2 weeks. Patients who are determined to be eligible based on the screening assessments will be randomized into the study and randomly allocated to treatment with PRM-151 or placebo. Patients entering the screening period on anti-fibrotic therapy (pirfenidone or nintedanib) should have been on treatment for at least 3 months, and on a stable dose for at least 4 weeks prior to the screening visit and are expected to remain on their specific dose and regimen throughout the study duration unless dose reduction or discontinuation is indicated for safety or tolerability reasons.

Patients entering the screening period of the study NOT on anti-fibrotic treatment (pirfenidone or nintedanib), either treatment naive or having previously taken and discontinued, must have been off such treatment for at least 4 weeks prior to the screening visit and during screening.

At the time of consent, if a patient is considering starting treatment with either nintedanib or pirfenidone, the patient should be advised of being on treatment for at least 3 months prior to screening.

For all patients receiving anti-fibrotic therapy, the investigator should document the dose, frequency, and duration of the anti-fibrotic drug. For patients not receiving anti-fibrotic therapy during the screening period, the investigator should document the reason(s). During the study, patients may initiate pirfenidone or nintedanib as rescue, if determined to be clinically indicated by the investigator. The investigator may consider discussing changes in anti-fibrotic therapy with the Medical Monitor throughout the study. The investigator is required to document the specific reason for introducing anti-fibrotic therapy in patients who were randomized into the study not on anti-fibrotic therapy.

Approximately 658 patients will be randomly assigned on a 1:1 basis to treatment with PRM-151 or placebo, as follows:

* PRM-151 Group: PRM-151 10 mg/kg IV infusion over 50-70 minutes on Days 1, 3, and 5, then one infusion Q4W for 48 weeks
* Placebo Group: Matched placebo IV infusion over 50-70 minutes on Days 1, 3, and 5, then one infusion Q4W for 48 weeks

The randomization will be stratified as follows:

* Concurrent use of nintedanib treatment versus pirfenidone treatment versus no concurrent treatment
* Region: China (including Hong Kong and Taiwan), North America (United States and Canada), Europe (including eastern Europe), Latin America, and Rest of World (including east Asia, Australia, and New Zealand)

All patients will have a final assessment visit at Week 52 (4 weeks after the final study drug infusion). Patients will be invited to enroll in an OLE study at this point (Study WA42294), and if they roll over into that study, the Week 52 visit will be considered their end of study visit. Patients who do not enroll in the OLE study will have their end of study visit at Week 56, in

addition to the Week 52 visit.

Intervention

Patients randomized to study drug will receive IV infusions of 10 mg/kg PRM-151 over approximately 50 to 70 minutes, with dose based on the patient*s weight taken at the same clinic visit (for loading or reloading doses, the weight taken at the first clinic visit for the first dose can be applied to the second and third doses).
Patients randomized to placebo will receive IV infusions of placebo over approximately 50-70 minutes.

Study burden and risks

PRM-151, a recombinant form of an endogenous human protein, was generally well tolerated in nonclinical toxicity studies and in Phase I and II clinical studies. Clinically and statistically significant positive effects with PRM-151 were observed in the Phase II IPF study, both for change in FVC (% predicted) and 6MWD through 28 weeks of treatment. Based on encouraging Phase I and II data in subjects with IPF, PRM-151 has the potential to be a well-tolerated, disease modifying treatment for a broad spectrum of fibrotic diseases, including IPF.
In the two Phase I studies of PRM-151 administered intravenously to normal volunteers and patients with IPF, no serious adverse events were reported and no other safety signals were seen. The single ascending dose study (PRM151A-11EU) tested dose levels as high as 20 mg/kg. The multiple ascending dose study (PRM151F-12GL) demonstrated that PRM-151 administered by 30-minute IV infusion on Days 1, 3, 5, 8, and 15 at up to 10 mg/kg was safe and well tolerated in subjects with IPF, with no serious adverse events noted in 57 days. In the Phase II study, PRM-151 was generally well tolerated through at least 6 months of treatment.
Risks associated with PRM-151 are inherent in it being the recombinant form of a naturally occurring human protein and consist of potential development of ADA and infusion reactions. PRM-151 has an endogenous counterpart; therefore, ADAs could develop that could potentially affect the efficacy of PRM-151 treatments in addition to having the potential to cross-react with endogenous hPTX-2.
PRM-151 is not a general immunosuppressant, and treatment with PRM-151 is not expected to increase rates of infection or adversely affect wound healing.
As with any protein therapeutic, the potential for reactions exists and safety procedures will be implemented, including careful monitoring of patients during infusions and of infusion sites. Appropriate personnel, medication, and other requirements for the treatment of potential infusion reactions will be required by the protocol. PRM-151 is an investigational agent and the potential benefits of PRM-151 as a therapy for IPF remain to be proven in clinical efficacy studies. (See Protocol, 1.3.1)

Contacts

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Hoffmann-La Roche

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* Signed Informed Consent Form
* Age 40-85 years, inclusive, at time of signing Informed Consent Form
* Ability to comply with the requirements of the study protocol, according to the investigator*s
best judgment
* Documented diagnosis of IPF per the 2018 ATS/ERS/JRS/ALAT Clinical Practice Guideline
* HRCT pattern consistent with the diagnosis of IPF, confirmed by central review of Chest
HRCT (available HRCT of acceptable quality performed within 12 months prior to screening
or obtained during the screening period) and central review of any available lung biopsy (LB)

* Minimum 6MWD of 150 meters with maximum use of 6 L/min at sea-level and up-to 8 L/min
at altitude (* 5000 feet [1524 meters] above sea level) of supplemental oxygen while
maintaining oxygen saturation of * 83% during the 6MWT during screening
* FVC * 45% predicted during screening as determined by the over-reader
* Forced expiratory volume in 1 second (FEV1)/FVC ratio * 0.70 during screening as determined by the over-reader
* DLCO * 30% and * 90% of predicted during screening (Hgb corrected or uncorrected) as determined by the over-reader
* If receiving pirfenidone or nintedanib treatment for IPF, the patient must have been on
treatment for at least 3 months and on a stable dose for at least 4 weeks prior to screening,
and during screening (with no contraindications according to local prescribing information)
* If not currently receiving nintedanib or pirfenidone treatment (either treatment naïve or
having previously taken and discontinued) must have discontinued such treatment
* 4 weeks prior to screening and during screening
If patient is considering starting treatment with either nintedanib or pirfenidone, patient
must be on treatment for at least 3 months prior to screening, provided there are no
contraindications according to local prescribing information.
* For women of childbearing potential: (excluding patients enrolling in Japan): agreement to remain abstinent (refrain from
heterosexual intercourse) or use contraception, as defined below:
Women must remain abstinent or use contraceptive methods with a failure rate of * 1%
per year during the treatment period and for 8 weeks after the final dose of PRM-151.
A woman is considered to be of childbearing potential if she is postmenarchal, has not
reached a postmenopausal state (>= 12 continuous months of amenorrhea with no identified cause other than menopause), and is not permanently infertile due to surgery
(i.e., removal of ovaries, fallopian tubes, and/or uterus) or another cause as determined
by the investigator (e.g., Müllerian agenesis). The definition of childbearing potential may
be adapted for alignment with local guidelines or regulations.
Examples of contraceptive methods with a failure rate of * 1% per year include bilateral tubal ligation, male sterilization, hormonal contraceptives that inhibit ovulation,
hormone-releasing intrauterine devices, and copper intrauterine devices.
Hormonal contraceptive methods must be supplemented by a barrier method.

The reliability of sexual abstinence should be evaluated in relation to the duration of the
clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence
(e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are
not adequate methods of contraception. If required per local guidelines or regulations,
locally recognized adequate methods of contraception and information about the
reliability of abstinence will be described in the local Informed Consent Form.
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23/Protocol WA42293, Version 2 (VHP)
* For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a
condom, and agreement to refrain from donating sperm, as defined below:
With a female partner of childbearing potential or pregnant female partner, men must
remain abstinent or use a condom during the treatment period and for 8 weeks after the
final dose of PRM-151 to avoid exposing the embryo. Men must refrain from donating
sperm during this same period.
The reliability of sexual abstinence should be evaluated in relation to the duration of the
clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence
(e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are
not adequate methods of preventing drug exposure. If required per local guidelines or
regulations, information about the reliability of abstinence will be described in the local
Informed Consent Form.
* Anticipated life expectancy of at least 12 months at baseline, according to the
investigator*s judgment
* Patient and investigator considered all medicinal treatment options and/or possibly lung
transplantation prior to considering participation in the study. If the patient is on a lung
transplant list, the investigator anticipates the patient will be able to complete the study prior
to transplant.
* For patients enrolled in the extended China enrollment phase:
current resident of mainland China, Hong Kong, or Taiwan, and of Chinese ancestry

Exclusion criteria

* Evidence of other known causes of interstitial lung disease (e.g., domestic and occupational
environmental exposures, connective-tissue disease, and drug toxicity)
* FVC% predicted value showing improvement in the 6-month period prior to screening and
including screening value, as assessed by the investigator
* Emphysema present on * 50% of the HRCT, or the extent of emphysema is greater than the
extent of fibrosis, according to central review of the HRCT
* Receiving nintedanib in combination with pirfenidone
* Received cytotoxic, immunosuppressive, cytokine modulating, or receptor antagonist
agents (including but not limited to methotrexate, azathioprine, mycophenolate mofetil,
cyclophosphamide, cyclosporine or other steroid sparing agent) within 4 weeks prior to or during screening
* Receiving systemic corticosteroids equivalent to prednisone * 10 mg/day or equivalent
within 2 weeks prior to or during screening
* Receiving strong inhibitor or inducer of CYP1A2 in patients taking pirfenidone
* Receiving potent inhibitor or inducer of P-gp in patients taking nintedanib
* Acute respiratory or systemic bacterial, viral, or fungal infection either during screening or
prior to screening and not successfully resolved 4 weeks prior to screening visit
* Positive interferon gamma release assay
- Test for tuberculosis during screening: Patients who have completed treatment for tuberculosis within 6 months prior to screening, and have no evidence of recurrent disease, do not need to
be tested
* Resting oxygen saturation of * 89% using up to 4 L/min of supplemental oxygen at sea
level and up-to 6 L/min at altitude (* 5000 feet [1524 meters] above sea level) during
screening
* Co-existing acute or chronic medical condition that, in the investigator*s opinion, would
substantially limit the ability to comply with study requirements or may influence any of the
safety or efficacy assessments included in the study
* Class IV New York Heart Association chronic heart failure
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24/Protocol WA42293, Version 2 (VHP)
* Historical evidence of left ventricular ejection fraction * 35%

* Presence of pulmonary hypertension that, in the investigator*s opinion, would substantially limit the ability to comply with study requirements or may influence any of
the safety or efficacy assessments included in the study
* Cardiopulmonary rehabilitation program based on exercise training that has been
completed within 8 weeks prior to screening or planned to start during the patient*s
enrollment in this trial
* History of smoking (including cigarette, cannabis, cigar, pipe and vaping) within 3 months
prior to or during screening
* History of alcohol or substance use disorder within 2 years prior to or during screening or known or
suspected active alcohol or substance-use disorder
* History of a malignancy within the 5 years prior to screening, with the exception of basal cell
or squamous cell skin neoplasms. In addition, a malignant diagnosis or condition that
occurred more than 5 years prior to screening, and any basal cell or squamous cell
neoplasm must be considered cured, inactive, and not under treatment.
* Unable to refrain from use of the following:
- Short acting bronchodilators (SABA) within 4 hours before pulmonary function, DLCO, and
6MWT assessments
- Once daily, long-acting bronchodilators within 24 hours before pulmonary function, DLCO,
and 6MWT assessments
- Twice daily, long-acting bronchodilators within 12 hours before pulmonary function testing,
DLCO, and 6MWT assessments
* Known post-bronchodilator response in FEV1 and/or FVC * 12% and * 200 mL, respectively
* Receipt of an investigational drug within 4 weeks, or 5 half-lives, whichever is longer, prior
to or during screening
* Previous treatment with PRM-151
* History of severe allergic reaction or anaphylactic reaction to a biologic agent including any allergies to the additives of the drug product.
* Clinically significant abnormality on ECG during screening that in the opinion of the investigator, may pose an additional risk in administering study drug to the patient
* Prolonged corrected QT interval > 450 ms (for men) or > 470 ms (for women) on ECG during screening, based on the Fridericia correction formula
* Clinically significant laboratory test abnormalities during screening (hematology, serum chemistry, and urinalysis) that, in the opinion of the

investigator, may pose an additional risk in administering study drug to the patient
* Any of the following laboratory abnormalities during screening:
- ALT and/or AST * 2.5 * upper limit of normal (ULN)
- Total bilirubin * 2 * ULN
* Pregnant or breastfeeding, or become pregnant during the study or within 8 weeks after the final dose of PRM-151
Women of childbearing potential must have a negative serum pregnancy test result within
30 days prior to initiation of study drug.
* Women of childbearing potential (Only for patients enrolling in Japan)
- A woman is considered to be of childbearing potential if she is postmenarchal, has not reached a postmenopausal state (>= 12 continuous months of amenorrhea with no identified cause other than menopause), and is not permanently infertile due to surgery (i.e., removal of ovaries, fallopian tubes, and/or uterus) or another cause as determined by the investigator (e.g., Müllerian agenesis).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2021
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Recombinant human Pentraxin-2 (PRM-151)
Generic name:	-

Ethics review

Approved WMO Date:	21-01-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-04-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-10-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	08-05-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-10-2022
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	EUCTR2020-000791-38-NL
ClinicalTrials.gov	NCT04552899

Register	ID
CCMO	NL75034.078.21