A Phase 3 Study Comparing Pomalidomide and Dexamethasone With or Without Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy With Both Lenalidomide and a Proteasome Inhibitor.
The APOLLO Study

Published: 26-04-2018
Last updated: 18-07-2024

The purpose of this study is to evaluate the effects of the addition of daratumumab to pomalidomide and dexamethasone in subjects with relapsed or refractory MM.1. Primary objectiveThe primary objective of this study is to compare PFS between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Plasma cell neoplasms
Study type	Interventional

Summary

ID

NL-OMON52783

Source
ToetsingOnline

Brief title
The APOLLO Study

Condition

- Plasma cell neoplasms

Synonym
Kahler's disease, plasma cell myeloma

Research involving
Human

Sponsors and support

Primary sponsor: European Myeloma Network (EMN)
Source(s) of monetary or material Support: Janssen Research & Development;LLC

Intervention

Keyword: comparative, multi-center, Multiple Myeloma, phase 3

Outcome measures

Primary outcome

Primary Endpoint

- * Progression-free survival

Secondary outcome

Secondary Endpoints

• Overall response rate

• VGPR or better

• Complete response (CR) or better

• MRD negativity rate

• Time to response

• Duration of response (DoR)

• Time to next therapy

• Overall survival

• Safety (adverse events)

• Scale and domain scores of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 item (EORTC QLQ-C30) (global health status, physical functioning, emotional functioning, fatigue, pain) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Multiple Myeloma Module (EORTC QLQ-MY20) (disease symptoms, side effects of treatment)

• European Quality of Life Five Dimensions Questionnaire (EQ-5D-5L) health utility values

• Immunomodulatory effects of daratumumab on T cells

• Daratumumab pharmacokinetic concentrations (Dara IV and Dara SC)

• Daratumumab and rHuPH20 immunogenicity in subjects who receive Dara SC

Study description

Background summary

Multiple myeloma (MM) is a malignant plasma cell disorder that is characterized by the production of monoclonal immunoglobulin in a majority of patients and that invades adjacent bone tissue. Common manifestations include bone pain, renal insufficiency, hypercalcemia, anemia, and recurrent infections.
Currently approved treatments for patients with relapsed/refractory MM include proteasome inhibitors (PIs) (eg, bortezomib, carfilzomib), immunomodulatory drugs (thalidomide, lenalidomide, or pomalidomide), histone deacetylase inhibitors, and monoclonal antibodies (elotuzumab, daratumumab). However, there is no cure, and current therapies only slow disease progression, prolong survival, and reduce symptoms. Although recent advances in the development of targeted therapeutics and stem cell transplantation have improved overall and event-free survival, the great majority of patients with myeloma will relapse and experience disease progression.
Daratumumab is a human IgG* monoclonal antibody that targets CD38, which is an important immunotherapy target due to its high expression on malignant plasma cells and low expression on other normal lymphoid and myeloid cells, and is an

important modulator of intracellular signaling. In November 2015, DARZALEX® (daratumumab) was approved by the U.S. FDA for the treatment of patients with MM who have received at least 3 prior lines of therapy, including a PI and an immunomodulatory drug (IMiD), or who are double-refractory to a PI and an IMiD agent. In May 2016, the European Commission granted approval of daratumumab for the monotherapy of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an IMiD and who demonstrated disease progression on the last therapy. In July 2016, the FDA granted a Breakthrough Therapy Designation to daratumumab in combination with lenalidomide (an IMiD agent) and dexamethasone, or bortezomib (a PI) and dexamethasone, for the treatment of patients with MM who have received at least 1 prior therapy.
The aim of this study (APOLLO) is to further investigate the efficacy and safety of a DaraPomDex combination in order to provide physicians with a novel therapeutic strategy for treating patients with relapsed/refractory MM. On 16 June 2017, DARZALEX® in combination with pomalidomide and dexamethasone was approved by the FDA for the treatment of patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a PI. However, DaraPomDex is not an approved regimen anywhere in the European Union (EU).

The approved way to give daratumumab is by intravenous (IV) infusion. In order to significantly shorten the infusion time and decrease the risk of infusion reactions, a new formulation, which combines daratumumab with a recombinant human hyaluronidase enzyme (rHuPH20), has been developed to allow daratumumab in liquid form to be given by a subcutaneous injection. This new way of giving daratumumab is not approved and is being evaluated in studies to determine how well it works compared to the type that is currently approved and given into the vein (IV). In this trial, daratumumab will be given subcutaneously.

Study objective

The purpose of this study is to evaluate the effects of the addition of daratumumab to pomalidomide and dexamethasone in subjects with relapsed or refractory MM.

1. Primary objective
The primary objective of this study is to compare PFS between treatment arms.

2. Secondary objectives
The secondary objectives of the study are the following:
• To compare Overall Response Rates (ORR) between treatment arms.
• To compare duration of response (DoR) between treatment arms.
• To compare time to next therapy between treatment arms.
• To compare Overall Survival (OS) between treatment arms.
• To assess the safety and tolerability of the investigational combination treatment.

• To assess the depth of response by analyzing Minimum Residual Disease (MRD) negativity rate for CR or better and for suspected CR/sCR.
• To compare health-related quality-of-life (HRQoL) and health utility between treatment arms
• To evaluate the immunomodulatory effects of daratumumab on T cells.
• To evaluate daratumumab pharmacokinetics and immunogenicity and immunogenicity and the immunogenicity of rHuPH20

Study design

This is a multicenter, Phase 3, randomized, open-label study comparing daratumumab, pomalidomide and low-dose dexamethasone (DaraPomDex) with pomalidomide and low-dose dexamethasone (PomDex) in subjects with relapsed or refractory MM who have received at least 1 prior treatment regimen with both lenalidomide and a PI and have demonstrated disease progression.
Approximately 302 subjects located in about 12 countries will be randomized in a 1:1 ratio to receive either DaraPomDex or PomDex. Treatment cycles have a duration of 28 days:
Pomalidomide will be administered at full dose of 4 mg orally (PO) on Days 1 through 21 of each 28-day cycle.
Daratumumab will be given at a dose of 1800 mg administered subcutaneously at weekly intervals (QW) for 8 weeks, then every 2 weeks (Q2W) for an additional 16 weeks, then every 4 weeks (Q4W) thereafter. Subjects will receive pre-infusion medications before infusions to mitigate potential IRRs.
Dexamethasone will be administered according to standard clinical practice and at a recommended total dose of 40 mg weekly for both treatment groups (20 mg weekly for subjects >=75 years of age).
Subjects will receive treatment until disease progression or unacceptable toxicity.
Drug administration and follow-up visits will occur more frequently for early cycles (e.g., weekly or bi-weekly) (see Table 7.2). Disease evaluations will occur every cycle and consist mainly of measurements of myeloma proteins. Other parameters may include bone marrow examinations, skeletal surveys, assessment of extramedullary plasmacytomas, and measurements of serum calcium corrected for albumin. Patient-reported outcome measures will be administered on Day 1 of each treatment cycle, prior to receiving treatment or any other assessment.
Assessment of myeloma response and disease progression will be conducted in accordance with the modified International Myeloma Working Group (IMWG) response criteria.
Survival status, subsequent antimyeloma treatment data, and PRO measures will be collected post-treatment.
The primary analysis of PFS will occur after 188 PFS events have been observed. Long-term survival follow-up and data collection will continue until approximately 166 deaths have been observed or 5 years after the last subject is randomized. Subjects benefiting from the study treatment can continue to receive study treatment after the CCO for the final OS analysis. For these subjects, study treatment will be available through continued access within the

current study until it is available through another source such as commercial availability with reimbursement, continued access through a long-term extension study, a patient access program, or after the last subject transitions into the long-term extension phase of the study up to 31 March 2024, whichever occurs first

Refer to protocol, table 7.3 on page 72

Intervention

Please refer to the section 7.2 of the protocol (TABLE 7.3: SCHEDULE OF EVENTS and TABLE 7.3.1)

Study burden and risks

Extract from protocol:
2.3.1 Known Potential Risks
Daratumumab
As of 30 June 2016, 3,147 subjects have been enrolled in studies using daratumumab via intravenous (IV) infusions; 762 subjects received daratumumab alone and 2,385 subjects received daratumumab in combination with other drugs used to treat MM. Given that daratumumab is not approved in Europe for the indication under study, not all the possible side effects and risks related to daratumumab are known and new side effects may occur. A description of the events observed when daratumumab was given via an IV infusion in combination with other drugs is provided below (see also Daratumumab IB).
Daratumumab IV Combination Studies
The safety profile of daratumumab in combination with standard background regimens (bortezomib, lenalidomide, pomalidomide, dexamethasone, melphalan, prednisone, thalidomide, carfilzomib) is consistent with those of the background regimens and single-agent daratumumab.
Among the 318 subjects treated with 16 mg/kg of daratumumab in combination with lenalidomide and dexamethasone in Study MMY3003 and Phase 2 of Study GEN503:
• Treatment-emergent adverse events (TEAE) leading to discontinuation of study treatment were reported in 27 subjects (9%).
• Seventeen subjects (5%) died within 30 days of last dose due to an AE.
• The most frequently reported TEAEs (reported in >=25% of subjects) were neutropenia (63%), diarrhea (48%), fatigue (36%), anemia (33%), cough (32%), upper respiratory tract infection (32%), muscle spasms (30%), constipation (29%), thrombocytopenia (28%), nasopharyngitis (27%), and nausea (26%). No TEAEs of tumor lysis syndrome, hemolysis, or transfusion reaction were reported.
• Serious adverse events (SAEs) were reported in 174 subjects (55%); the most frequently reported SAEs were pneumonia (9%), influenza (4%), febrile neutropenia (4%), pyrexia (3%), bronchitis (3%), pulmonary embolism (3%), lower respiratory tract infection (2%), and diarrhea (2%).
• Grade 3 or 4 TEAEs were reported in 267 subjects (84%); the most frequently

reported Grade 3 or 4 TEAEs were neutropenia (56%), anemia (14%), and thrombocytopenia (14%).
• Infections or infestations were reported in 87% of subjects. The most frequently reported were upper respiratory tract infection (32%), nasopharyngitis (27%), bronchitis (17%), pneumonia (15%), and respiratory tract infection (11%).
Among the 243 subjects treated in Study MMY3004 with daratumumab in combination with bortezomib and dexamethasone:
• Treatment-emergent adverse events leading to discontinuation of study treatment were reported in 22 subjects (9%).
• Fourteen deaths (6%) were reported within 30 days after the last dose. Twelve subjects died due to TEAEs and 2 subjects died due to disease progression.
• The most frequently reported TEAEs (reported in >=25% of subjects) were thrombocytopenia (60%), peripheral sensory neuropathy (49%), diarrhea (34%), upper respiratory tract infection (30%), anemia (28%), and cough (27%).
• Serious adverse events were reported in 118 subjects (49%); the most frequently reported were pneumonia (21 subjects; 9%), anemia, bronchitis, thrombocytopenia, atrial fibrillation, upper respiratory tract infection (3% each), and pyrexia (2%).
• Grade 3 or 4 TEAEs were reported in 193 subjects (79%); the most frequently reported Grade 3 or 4 TEAEs were thrombocytopenia (45%), anemia (15%), and neutropenia (13%).
• Infections or infestations were reported in 73% of subjects. The most frequently reported were upper respiratory tract infection (30%), pneumonia (14%), and bronchitis (13%).
Infusion-Related Reactions (IRR)
Infusion-related reactions were reported in approximately half of all subjects treated with daratumumab and usually occurred with the first infusion and during or within the first few hours of the start of the infusion. Signs and symptoms of IRRs may include respiratory symptoms, such as stuffy nose, cough, throat irritation, as well as chills, vomiting, and nausea. Less common symptoms are difficulty breathing (wheezing), runny nose, fever, chest discomfort, itching, hypotension, or hypertension. Most of the observed IRRs were mild or moderate, and ended by temporarily stopping the infusion and by providing medication. Severe reactions have occurred including bronchospasm, hypoxia, dyspnea, hypertension, and laryngeal and pulmonary edema. See Section 6.1.5 for information regarding the management of IRRs and Section 7.3.1 and Section 7.3.2 for recommendations concerning the use of pre- and post-infusion medication, respectively.

Daratumumab for Subcutaneous Injection (Dara MD and Dara SC)
Study MMY1004 is a Phase 1b study to assess the safety and pharmacokinetics of SC administration of daratumumab. In Part 1 of this study, a mix and-deliver SC presentation (Dara MD) of the currently approved daratumumab IV formulation was used: rHuPH20 and daratumumab were mixed just prior to delivery. Up to 90 mL of Dara MD was administered SC weekly for 8 weeks, every 2 weeks for 16 weeks, and then every 4 weeks thereafter. Subjects in Part 2 of this study receive the

final formulation of daratumumab for SC administration in which daratumumab has been co-formulated with recombinant human hyaluronidase (rHuPH20 [referred to as Dara CF or Dara SC in this protocol]). Dara CF is supplied as a single, pre-mixed vial (120 mg/mL daratumumab containing 30,000 U rHuPH20, 15 mL injection volume for a 1800 mg dose level). It is administered at 1800 mg following the same schedule as Dara MD and can be administered in 3 to 5 minutes by manual SC injection in the periumbilical area of the abdominal wall. Preliminary data from this study show that SC administration is feasible and has a substantially shortened administration time compared with standard IV administration. Fifty-three (53) subjects who received Dara MD (1200 mg [n=8]; 1800 mg [n=45]) between November 2015 and August 2016 were evaluable for safety and efficacy. Treatment-emergent adverse events for Dara MD in this study appeared to be similar to those reported in single-agent studies of Dara IV (Lokhorst 2015, Lonial 2016. After a median treatment duration of 2.6 months (range 0.7-12) for the 1200 mg cohort and 3.4 months (range 0.7-8.6) for the 1800 mg cohort, the key safety findings are as follows:
For subjects receiving Dara MD, the incidence of all-grade IRRs was 13% and 24% in the 1200 mg and 1800 mg cohorts, respectively).
• IRRs were mostly Grade 1 or 2 and included chills, pyrexia, non-cardiac chest pain, edema of the tongue, nausea, vomiting, dyspnea, wheezing, flushing, hypertension, hypotension, oropharyngeal pain, rash, paresthesia and pruritus. Only 1 subject (in the 1200 mg cohort) developed Grade 3 dyspnea; no Grade 4 IRR was reported in either cohort.
• All IRRs developed during or within 6 hours of the start of the first Dara MD infusion and were controlled with antihistamine, corticosteroid, or bronchodilator treatment and did not result in treatment discontinuation. No IRRs were reported on subsequent infusions.
• The most frequently reported TEAEs (?20% of all subjects) were upper respiratory tract infection (1200 mg: 38%; 1800 mg: 22%), insomnia (1200 mg: 38%; 1800 mg: 11%), decreased appetite (1200 mg: 38%; 1800 mg: 7%), thrombocytopenia (1200 mg: 38%; 1800 mg: 18%), viral upper respiratory tract infection (1200 mg: 25%; 1800 mg: 13%), vomiting (1200 mg: 25%; 1800 mg: 13%), hyperuricaemia (1200 mg: 25%; 1800 mg: 2%), hypokalaemia (1200 mg: 25%; 1800 mg: 4%), blood creatinine increased (1200 mg: 25%; 1800 mg: 4%), anemia (1200 mg: 25%; 1800 mg: 33%), fatigue (1200 mg: 25%; 1800 mg: 20%) pyrexia (1200 mg: 25%; 1800 mg: 27%), diarrhea (1200 mg: 25%; 1800 mg: 22%), headache (1200 mg: 25%; 1800 mg: 18%), cough (1200 mg: 25%; 1800 mg: 13%), epistaxis (12

Contacts

Public
European Myeloma Network (EMN)

Erasmas University Hospital, s-Gravendijkwal 230

Rotterdam 3015CE
NL
Scientific
European Myeloma Network (EMN)

Erasmas University Hospital, s-Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Males and females at least 18 years of age.
2. Voluntary written informed consent before performance of any study-related procedure.
3. Subject must have measurable disease of MM as defined by the criteria below:
• IgG multiple myeloma: Serum M protein level >=1.0 g/dL or urine M-protein level >=200 mg/24 hours, or
• IgA, IgD, IgE, IgM multiple myeloma: Serum M-protein level >=0.5 g/dL or urine M-protein level >=200 mg/24 hours; or
• Light chain multiple myeloma, for subjects without measurable disease in the serum or urine: Serum immunoglobulin
FLC >=10 mg/dL and abnormal serum immunoglobulin kappa lambda FLC ratio.
4. Subjects must have received prior anti-myeloma treatment. The prior treatment must have included both a PI- and
lenalidomide-containing regimens. The subject must have had a response (ie, PR or better based on the investigator*s
determination of response as defined by the modified IMWG criteria) to prior therapy.
5. Subjects must have documented evidence of PD based on the investigator*s determination of response as defined by

the modified IMWG criteria on or after the last regimen.
6. Subjects who received only 1 line of prior treatment must have demonstrated PD on or within 60 days of completion of
the lenalidomide containing regimen (ie, lenalidomide refractory).
7. Eastern Cooperative Oncology Group (ECOG) performance status score of <=2.
8. Willingness and ability to participate in study procedures.
9. For subjects experiencing toxicities resulting from previous therapy, the toxicities must be resolved or stabilized to
<=Grade 1.
10. All of the following laboratory test results during Screening:
a) Absolute neutrophil count >=1.0 × 109/L;
b) Hemoglobin level >=7.5 g/dL (>=4.65 mmol/L) (transfusions are not permitted to reach this level);
c) Platelet count >=75 × 109/L in subjects in whom <50% of bone marrow nucleated cells are plasma cells and platelet count
>=50 x 109/L in subjects in whom >=50% of bone marrow nucleated cells are plasma cells (transfusions are not permitted
to reach this level);
d) Alanine aminotransferase (ALT) level <=2.5 times the upper limit of normal (ULN);
e) Aspartate aminotransferase (AST) level <=2.5 x ULN;
f) Total bilirubin level <=1.5 x ULN, (except for Gilbert Syndrome: direct bilirubin <=1.5 × ULN);
g) Creatinine clearance >=30 mL/min (Appendix 6);
h) Serum calcium corrected for albumin <=14.0 mg/dL (<=3.5 mmol/L), or free ionized calcium <=6.5 mg/dL (<=1.6 mmol/L).
11. Criterion (letter *g*) modified per Amendment 2:
11.1 Reproductive Status
a) Women of childbearing potential (WOCBP) must have 2 negative serum or urine pregnancy tests, one 10-14 days prior
to start of study treatment and one within 24 hours prior to the start of study treatment. Females are not of reproductive
potential if they have been in natural menopause for at least 24 consecutive months, or have had a hysterectomy and/or
bilateral oophorectomy.
b) Women must not be breastfeeding.
c) WOCBP must agree to follow instructions for methods of contraception for 4 weeks before the start of study treatment,
for the duration of study treatment, and for 3 months after cessation of daratumumab or 4 weeks after cessation of
pomalidomide, whichever is longer.
d) Males who are sexually active must always use a latex or synthetic condom during any sexual contact with females of
reproductive potential, even if they have undergone a successful vasectomy. They must also agree to follow instructions
for methods of contraception for 4 weeks before the start of study treatment, for the duration of study treatment, and for a

total of 3 months post-treatment completion.
e) Male subjects must not donate sperm for up to 90 days post-treatment completion.
f) Female subject must not donate eggs for up to 90 days post-treatment completion.
g) Azoospermic males and WOCBP who are not heterosexually active are exempt from contraceptive requirements.
However, WOCBP will still undergo pregnancy testing as described in this section.
Highly effective methods of contraception have a failure rate of <1% when used consistently and correctly. Subjects must agree to the use of 2 methods of contraception, with 1 method being highly effective and the other method being additionally effective.
Because of the embryo-fetal risk of pomalidomide, all subjects must adhere to the pomalidomide pregnancy prevention program applicable in their region. Investigators should comply with the local label for pomalidomide for guidance on subject education and ensure that all subjects adhere to the local Pomalidomide Risk Evaluation Mitigation Strategy (REMS) program.
When no local pomalidomide REMS program exists, subjects must adhere to the pomalidomide Global Pregnancy Prevention Plan.

Exclusion criteria

1. Previous therapy with any anti-CD38 monoclonal antibody.
2. Previous exposure to pomalidomide.
3. Subject has received anti-myeloma treatment within 2 weeks or 5 pharmacokinetic half-lives of the treatment, whichever is longer, before the date of randomization. The only exception is emergency use of a short course of corticosteroids (equivalent of dexamethasone 40 mg/day for a maximum of 4 days) for palliative treatment before Cycle 1, Day 1 (C1D1).
4. Previous allogenic stem cell transplant; or autologous stem cell transplantation (ASCT) within 12 weeks before C1D1.
5. History of malignancy (other than MM) within 3 years before the date of randomization (exceptions are squamous and basal cell carcinomas of the skin, carcinoma in situ of the cervix or breast, or other non-invasive lesion that in the opinion of the investigator, with concurrence with the Sponsor's medical monitor, is considered cured with minimal risk of recurrence within 3 years).
6. Clinical signs of meningeal involvement of MM.
7. Chronic obstructive pulmonary disease (COPD) with a Forced Expiratory Volume in 1 second (FEV1) <50% of predicted normal.
Note that FEV1 testing is required for subjects suspected of having

COPD and subjects must be excluded if FEV1 <50% of
predicted normal. (Appendix 4).
8. Clinically significant cardiac disease, including:
a) Myocardial infarction within 6 months before C1D1, or unstable or
uncontrolled condition (eg, unstable angina, congestive heart
failure, New York Heart Association Class III-IV).
b) Cardiac arrhythmia (Common Terminology Criteria for Adverse Events [CTCAE]
Grade 3 or higher) or clinically significant
electrocardiogram (ECG) abnormalities.
c) Electrocardiogram showing a baseline QT interval as corrected QTc >470 msec.
9. Criterion modified per Amendment 2:
9.1 Known:
a) Active hepatitis A
b) To be seropositive for hepatitis B (defined by a positive test for
hepatitis B surface antigen [HBsAg]). Subjects with resolved infection (ie,
subjects who are positive
for antibodies to hepatitis B core antigen [antiHBc] and/or antibodies
to hepatitis B surface antigen [antiHBs]) must be screened using real-time
polymerase chain
reaction (PCR) measurement of hepatitis B virus (HBV) DNA levels. Those
who are PCR positive will be excluded. EXCEPTION: Subjects with serologic
findings
suggestive of HBV vaccination (antiHBs positivity as the only serologic
marker) AND a known history of prior HBV vaccination, do not need to be tested
for HBV
DNA by PCR.
c) To be seropositive for hepatitis C (except in the setting of a sustained
virologic response, defined as aviremia at least 12 weeks after completion of
antiviral therapy).10. Criterion Revised per Amendment 2
10.1 Known to be seropositive for human immunodeficiency virus.
11. Gastrointestinal disease that may significantly alter the absorption of
pomalidomide.
12. Subject has plasma cell leukemia (>2.0 × 109/L circulating plasma cells by
standard differential) or Waldenström*s
macroglobulinemia or POEMS syndrome (polyneuropathy, organomegaly,
endocrinopathy, monoclonal protein, and skin changes) or
amyloidosis.
13. Any concurrent medical or psychiatric condition or disease (eg, active
systemic infection, uncontrolled diabetes, acute diffuse
infiltrative pulmonary disease) that is likely to interfere with the
study procedures or results or that, in the opinion of the investigator,
would constitute a hazard for participating in this study.
14. Ongoing >=Grade 2 peripheral neuropathy.
15. Subject had >=Grade 3 rash during prior therapy.
16. Subject has had major surgery within 2 weeks before randomization, or has
not fully recovered from an earlier surgery, or has
surgery planned during the time the subject is expected to participate

in the study or within 2 weeks after the last dose of study drug administration. Note: subjects with planned surgical procedures to be conducted under local anesthesia may participate. Kyphoplasty or vertebroplasty are not considered major surgery.
17. Pregnant or nursing women.
18. Subject has known allergies, hypersensitivity, or intolerance to any of the study drugs, hyaluronidase, monoclonal antibodies, human proteins, or their excipients (refer to daratumumab IB), or known sensitivity to mammalian-derived products.
19. Subject was vaccinated with live vaccines within 4 weeks prior to randomization.
8°*

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):	11-10-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Imnovid
Generic name:	pomalidomide
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Not available
Generic name:	Daratumumab co-formulated with recombinant human hyaluronidase (rHuPH20)
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Not available
Generic name:	Dexamethasone

Ethics review

Approved WMO Date:	26-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	08-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date: 07-01-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 01-06-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 06-06-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 03-08-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 04-02-2022

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 17-02-2022

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 22-07-2022

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 16-02-2023

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 19-07-2023

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date:	06-03-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-001618-27-NL
CCMO	NL62783.029.17