A Phase 1 first-in-human dose-escalation and dose-expansion study of BMF-219, an oral, covalent, menin inhibitor, in adult patients with acute leukemia (AL), diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM), and chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL)

Published: 31-10-2022
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This study has been transitioned to CTIS with ID 2024-515744-23-00 check the CTIS register for the current data. The primary objectives of the study are to:Determine the OBD(s) and RP2D's) of BMF-219 monotherapy administered daily based on...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON55976

Source
ToetsingOnline

Brief title
COVALENT-101

Condition

- Leukaemias

Synonym
blood cancer, Leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Biomea Fusion Inc.
Source(s) of monetary or material Support: Biomea Fusion Inc.

Intervention

Keyword: BMF-219

Outcome measures

Primary outcome

Determine the OBD and RP2D of BMF-219 monotherapy (all cohorts).

Note that the OBD and RP2D may differ between Arm A and Arm B in Cohort 1.

-The OBD/RP2D will be determined based on evaluation of all available pharmacokinetics (PK)/pharmacodynamics (PD), target engagement, safety, and tolerability data.

- Escalation to the maximum tolerated dose (MTD) will not be performed if the OBD/RP2D can be identified at a lower level. Specifically, the maximum dose to be administered will not exceed more than one dose level above the OBD. Should dose limiting toxicity (DLT) be encountered at a dose level below the OBD/RP2D, the MTD will be defined as the highest dose that is not expected to cause DLT in more than 20% of subjects.

Secondary outcome

Evaluate the safety as expressed by treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs).

- Adverse Events (AEs) and SAEs will be graded according to the NCI -CTCAE v5.0.

Determine maximum observed plasma concentration (Cmax), time to reach maximum observed concentration (Tmax), and area under plasma-concentration time curve from time 0 to time of last quantifiable concentration (AUC0-last) of BMF-219.

-Cmax, Tmax, and AUC0-last of BMF-219.

Evaluate the efficacy of BMF-219 as measured by complete response rate (CRR) (Cohort 1) or objective response rate (ORR) (Cohorts 2, 3, and 4) per Investigator assessment as per corresponding response criteria

• Complete response rate (CRR) (all cohorts)

• Complete response rate composite (CRRc) (Cohorts 1 and 4)

• ORR (all cohorts)

Assess additional evidence of antitumor activity per Investigator assessment as per corresponding response criteria.

• Duration of complete response (DOCR) (all cohorts)

• Duration of complete response composite (DOCRc) (Cohorts 1 and 4)

• Duration of response (DOR) (all cohorts)

• Disease control rate (DCR) (Cohorts 2, 3, and 4)

• Duration of disease control (DDC) (Cohorts 2, 3, and 4)

• Time to progression (TTP) (Cohorts 2, 3, and 4)

• Relapse-free survival (RFS)/progression-free survival (PFS) (all cohorts)

• Time to Response (all cohorts)

• Time to Complete Response (TTCR) (all cohorts)

• Overall survival (OS) (all cohorts)

Study description

Background summary

Biomea Fusion is developing BMF-219, an orally bioavailable, covalent, small molecule, menin inhibitor for the treatment of acute leukemia and other menin-dependent malignancies. BMF-219 disrupts a key oncogenic interaction with MLL1-fusion proteins resulting from gene rearrangements in the MLL1 gene locus, and with MLL1-wt proteins in the presence of NPM1 and other mutations, respectively, as illustrated in Figure 2 below. Disruption of this interaction with small-molecule inhibitors or interference of menin protein expression via genetic intervention effectively suppresses uncontrolled cancer cell growth and induces both apoptotic death and cell differentiation as evidenced by induction of differentiation markers in treated leukemia cells (Krivtsov et al, 2019; Klossowski et al, 2020; Dzama et al, 2020).

Nonclinical studies of BMF-219 performed by Biomea Fusion have confirmed the critical nature of menin function in DLBCL and MM. Specifically, single-agent BMF-219 treatment also dramatically reduced tumor growth ex vivo in two primary DLBCL specimens, one cMYC-amplified (from a subject who initially responded, then progressed on R-EPOCH) and the other a triple-hit tumor (from a subject who initially responded, then progressed on R-CHOP). Of note, BMF-219 was as effective in inhibiting the growth of these primary DLBCL specimens ex vivo as in its inhibition of MLL1 fusion-positive and NPM1-mutant primary AML specimens ex vivo.

BMF-219 was shown in parallel studies employing the MLL1 fusion-containing acute leukemia cell line MOLM13 to extinguish both cMYC and BCL2 transcripts to barely detectable levels at sub-micromolar concentrations. Consistent with these findings, cMYC target genes were substantively downregulated in AML PDX mouse models treated with BMF-219. Elucidation of the mechanism(s) by which menin inhibition modulates cMYC and BCL2 transcription in malignancies with varied genetic backgrounds is the focus on ongoing nonclinical studies at Biomea Fusion.

In contrast to the robust anti-DLBCL activity observed with BMF-219, reversible

menin inhibitors showed minimal-to-modest efficacy in the same in vitro and ex vivo models.

Study objective

This study has been transitioned to CTIS with ID 2024-515744-23-00 check the CTIS register for the current data.

The primary objectives of the study are to:
Determine the OBD(s) and RP2D's) of BMF-219 monotherapy administered daily based on evaluation of all available PK/ PD, target engagement, safety, and tolerability data. Note that the OBD and RP2D may differ between arms and/or cohorts.

The secondary objectives of the study are to:
1. Evaluate the safety as expressed by treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs). [Time Frame: During treatment and up to approximately 28 days after treatment discontinuation, or until immediately before the initiation of another anticancer therapy, whichever occurs first.] (all cohorts)
2. Determine Cmax, Tmax and AUC0-last. [Time Frame: Blood samples for determination of BMF-219 concentration will be collected during Cycle 1 and Cycle 2] (all cohorts)
3. Evaluate the efficacy of BMF-219 as measured by CRR (Cohort 1) or ORR (Cohorts 2, 3, and 4) per Investigator assessment based on:
* Cohort 1: per modified Cheson (2003) criteria in AML or the NCCN Clinical Practice Guidelines, ALL (Version 1.2022) (Appendix 14.11)
* Cohort 2: Revised criteria for response assessment of lymphoma (Cheson, 2014)
* Cohort 3: International Myeloma Working Group (IMWG) response criteria (Kumar, 2016)
* Cohort 4: iwCLL guidelines (Hallek, 2018)
4. Assess additional evidence of antitumor activity as measured by the following based on the applicable guidelines above:
* Cohort 1: CRR, complete response rate composite (CRRc), DOCR, DOCRc, DOR, time to relapse, RFS, time to response, TTCR, and OS
* Cohort 2: CRR, DOCR, DOR, DCR, DDC, TTP, PFS, time to response, TTCR, and OS
* Cohort 3: CRR, DOCR, DOR, DCR, DDC, TTP, PFS, time to response, TTCR, and OS
* Cohort 4: CRR, CRRc, DOCR, DOCRc, DOR, DCR, DDC, TTP, PFS, time to response, TTCR, and OS

The following exploratory objectives are also to be examined:
1. Characterize the PD effects of BMF-219 in subjects with AL (Cohort 1), DLBCL (Cohort 2), MM (Cohort 3), and CLL/SLL (Cohort 4) by the assessment of:
* Changes in the patterns of gene expression in BMF-219-treated tumor cells
2. Evaluate both gene mutation status and global gene expression profiles in BMF-219-treated leukemia cells, including subclonal population analysis to explore predictors of anti-leukemia activity and/or resistance (Cohort 1)

3. Evaluate DLBCL histology, DLBCL subtype (germinal center B-cell [GCB] or non-GCB), *double hit* (DH-DLBCL) and *triple hit,* (TH-DLBCL) as well as *double expressor* (DEDLBCL) and *triple expressor* (TH-DLBCL) status in all subjects to explore predictors of anti-tumor activity and resistance (Cohort 2)
4. Correlational studies to evaluate anti-myeloma response as related to:
* Cytogenetic and fluorescence in situ hybridization (FISH) prognostic markers including p53 abnormalities and chromosomal aberrations (e.g., del 17p, t(4;14), t(14;16), del 13) and other MM cytogenetic classifications
* Gene expression and plasma protein levels
* Time since initial diagnosis of active myeloma
* Lytic lesions as measured by imaging (Cohort 3)
5. Assess minimal residual disease (MRD) status in R/R AL subjects who achieve CR or Cri (Cohort 1), and R/R MM subjects who achieve CR, and stringent complete response (sCR) (Cohort 3), and in R/R CLL/SLL subjects who achieve CR/Cri or PR (Cohort 4)
6. Food-effect studies in subjects with DLBCL (Cohort 2). MM (Cohort 3) and CLL/SLL (Cohort 4) enrolled at Dose Levels 2, 3 and 4 during dose escalation and in the expansion cohorts
7. Assess the effects of BMF-219 on glycemic control for subjects with diabetes by measuring blood glucose, change in hemoglobin A1c (HbA1c) levels and blood C-peptide levels (all cohorts)

Study design

This Phase 1, FIH, multi-site, open-label, dose-escalation and expansion study of BMF-219, acovalent, small molecule, menin inhibitor, will determine the safety and tolerability, PK/PD, and clinical activity of escalating doses of BMF-219 administered orally daily in 28-day cycles. using
an ATD in adult subjects (>=18 years of age) with R/R acute leukemia including ALL, AML, and AMPL (Cohort 1), R/R DLBCL (Cohort 2), R/R MM (Cohort 3), and R/R CLL/SLL (Cohort 4). The dose escalation will follow a modified Fibonacci sequence. The study schema is shown in
Figure 3 of the study protocol.

• In Cohort 1, the 3+3 dose escalation portion will enroll at least 2/3 of subjects who are menin inhibitor naïve with confirmed MLL1r (KMT2A) genetic alteration and no more than 1/3 of subjects who are menin inhibitor experienced with confirmed MLL1r (KMT2A) genetic alterations (Subcohorts are described in Table 9 of the study protocol). The dose expansion portion of Cohort 1 will enroll subjects who are menin-inhibitor naïve grouped based on their mutational status and subjects who are menin-inhibitor experienced agnostic of mutational status. One or more dose levels/dosages (QD or BD) may be explored in a parallel or staggered fashion and one or more dose levels administered under different fed conditions may also be explored. Cohort 1 will selectively enroll subjects who are not (Arm A) or are (Arm B) receiving drugs that are moderate or strong inhibitors of CYP3A4 activity (see Section 8.12.3 of the study protocol).

• In Cohorts 2, 3, and 4, the dose escalation and dose expansion portions will enroll subjects agnostic of genetic mutational status. A food effect substudy will be conducted in Cohorts 2, 3, and 4. Cohorts 2, 3, and 4 will selectively enroll subjects who are not receiving drugs that are moderate or strong inhibitors of CYP3A4 activity (see Section 8.12.3 of the study protocol).

Within each cohort, the dose-escalation portion will identify the OBD(s) and/or RP2D(s) of BMF-219. Thereafter, in the expansion cohort portion for each of the 4 indications, subjects will be enrolled and treated at their respective OBD or RP2D to further evaluate the safety, tolerability, and clinical activity of BMF-219.

Intervention

For acute leukemia (Cohort 1), the starting dose of BMF-219 to be administered to the first cohort of subjects in the dose escalation portion is 325 mg QD (Arm A: Subjects who are not receiving a moderate or strong CYP3A4 inhibitor) or 75 mg QD (Arm B: Subjects who are receiving a moderate or strong CYP3A4 inhibitor) administered orally.
For DLBCL (Cohort 2), MM (Cohort 3) and CLL/SLL (Cohort 4) the starting dose of BMF-219 will be 325 mg QD. These cohorts will undergo independent single-arm dose escalations. All subjects participating in Arm A (Cohorts 1, 2, 3 or 4) will use the same escalation scheme, to identify the OBD/RP2D of BMF-219 for each indication, and they must not be receiving drugs that inhibit CYP3A4 activity.

Study burden and risks

The burden and risk consist mainly of extra time spent compared to standard treatment and side effects, and the risks of medical evaluation, including biopsy and MRI/CT scans.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Read, understood, and provided written informed consent and, if applicable, Health Insurance Portability and Accountability Act (HIPAA) authorization by subject or legal guardian after the nature of the study has been fully explained and must be willing to comply with all study requirements and procedures including DLBCL tumor biopsies (Cohort 2), serial bone marrow and peripheral blood sampling.
2. Males and females of age: >= 18 years
3. All subjects must have histologically or pathologically confirmed diagnosis of their malignancy and/or measurable R/R disease, as follows:
a. Cohort 1 only: Refractory or relapsed acute leukemia defined as > 5% blasts in the bone marrow or reappearance of blasts in the peripheral blood (as defined by the NCCN in the NCCN Clinical Practice Guidelines in Oncology [NCCN Guidelines®] for Acute Lymphoblastic Leukemia [Version 2.2021] and Acute Myeloid Leukemia [Version 3.2021]) Specific mutational statuses may be required for allocation to a specific subcohort.
b. Cohort 2 only: Previously treated, pathologically confirmed de novo DLBCL, or DLBCL transformed from previously indolent lymphoma (e.g., follicular lymphoma) with documented clinical or radiological evidence of progressive or persistent disease. At study entry, subjects must have measurable disease as per the revised criteria for response assessment of lymphoma (Cheson, 2014).
c. Cohort 3 only: Measurable MM based on at least one (1) of the following:
i. Serum M-protein >= 0.5 g/dL by serum protein electrophoresis (SPEP) (for an IgA-based myeloma, preferably by a quantitative serum IgA level)
ii. Urinary M-protein excretion >= 200 mg/24 hours
iii. Free light chain MM: Serum free light chain (sFLC) >= 10 mg/dL (100 mg/L),

provided serum FLC ratio is abnormal
iv. Of note, subjects without measurable disease in serum or urine, but with plasmacytoma(s) >= 2.0 cm are eligible
d. Cohort 4 only: Previously treated CLL/SLL with active disease meeting any of the following
conditions per the iwCLL 2018 criteria
i. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia
ii. Massive (i.e., >= 6 cm below the left costal margin) or progressive or symptomatic splenomegaly
iii. Massive nodes (i.e., >= 10 cm in longest diameter) or progressive or symptomatic lymphadenopathy
iv. Progressive lymphocytosis with an increase of >= 50% over a 2-month period, or lymphocyte doubling time (LDT) < 6 months. LDT can be obtained by linear regression extrapolation of absolute lymphocyte counts obtained at intervals of 2 weeks over an observation period of 2 to 3 months; subjects with initial blood lymphocyte counts < 30 × 109/L may require a longer observation period to determine the LDT. Factors contributing to lymphocytosis other than CLL/SLL (e.g., infections, steroid administration) should be excluded
v. Autoimmune complications including anemia or thrombocytopenia poorly responsive to corticosteroids
vi. Symptomatic or functional extranodal involvement (e.g., skin, kidney, lung, spine)
vii. Disease-related symptoms as defined by any of the following:
a. Unintentional weight loss >= 10% within the previous 6 months
b. Significant fatigue (i.e., ECOG PS 2 or worse; cannot work or unable to perform usual activities)
c. Fevers >= 100.5°F or 38.0°C for 2 or more weeks without evidence of infection
d. Night sweats for >= 1 month without evidence of infection
4. Subjects must be refractory or must have progressed on, or following discontinuation of the most recent anti-cancer therapy, with the following considerations:
a. Cohort 1 only: Have failed or are ineligible for any approved standard of care therapies, including HSCT
b. Cohort 2 only: Must have received at least 2 previous systemic regimens for the treatment of their de novo or transformed DLBCL (i.e., transformed from a previously diagnosed indolent lymphoma [e.g., follicular lymphoma]) including:
i. at least 1 course of anthracycline-based chemotherapy (unless absolutely contraindicated due to cardiac dysfunction, in which case other active agents such as etoposide, bendamustine, or gemcitabine must have been given), and
ii. at least 1 course of anti-CD20 immunotherapy (e.g., rituximab), unless contraindicated due to severe toxicity
Note: Subjects who were considered ineligible for standard multi-agent immunochemotherapy must have received at least 2 prior treatment regimens including at least 1 course of anti-CD20 antibodies and must have been approved by the Medical Monitor. Prior stem cell transplantation is allowed; induction,

consolidation, stem cell collection, preparative regimen, and transplantation ± maintenance are considered a single line of therapy. CAR-T therapy is allowed, and it is considered a prior line of therapy. Subjects with either persistent or progressive disease after discontinuing the most recent line of therapy may be eligible for participation.
c. Cohort 3 only: Must have received at least 3 anti-MM regimens including proteasome inhibitor (e.g., bortezomib or carfilzomib) and immunomodulatory drug (IMiD) (e.g., lenalidomide or pomalidomide) therapy. Note: Relapsed-and-refractory MM is defined as relapse of disease in subjects who must have achieved minimal response (MR) or better, which either becomes non-responsive while on salvage therapy, or progresses within 60 days of last therapy.
d. Cohort 4 only: Must have received at least 2 prior systemic treatment regimens.
5. ECOG PC of 0-2 and an estimated expected life expectancy of > 3 months in the opinion of the Investigator.
6. Adequate liver function: serum bilirubin <= 1.5x upper limit of normal (ULN) except for Gilbert*s syndrome or non-hepatic origin such as hemolysis (who must have a total bilirubin < 3x ULN); aspartate aminotransferase (AST) and alanine aminotransferase (ALT) <= 2x ULN (those subjects with known liver involvement of their disease and ALT and AST < 5x ULN may be enrolled, subject to Medical Monitor approval).
7. Adequate renal function: estimated creatinine clearance (eCrCl) >= 60 mL/min (Cohort 1) or eCrCl >= 30 mL/min (Cohorts 2, 3, and 4) using the Cockcroft-Gault equation
8. Subjects in Cohorts 2 ,3 and 4 must have the following hematologic parameters independent of transfusion and/or blood product support at least 5 days prior to laboratory testing:
a. Absolute neutrophil count (ANC) >= 500 /mm3
b. Platelet count >= 50,000 /mm3 (Cohorts 2 and 3) / >= 30,000 /mm3 (Cohort 4) (see Section 7.1).
c. Hemoglobin >= 8.0 g/dL.
Note: subjects who have cytopenias due to significant bone marrow infiltration do not have to meet hematologic eligibility criteria. (Significant bone marrow infiltration is defined as > 50% disease involvement.)
9. Both men and women of childbearing potential or their partners must use adequate birth control measures during the course of the trial and for at least 90 days after discontinuing study treatment. Subjects and/or partners who are surgically sterile or postmenopausal are exempt from this requirement.
• Females are to be not pregnant, non-lactating, and can be postmenopausal (defined as amenorrheic for at least 1 year while not taking oral contraceptives [OCPs] without an alternative cause). Females of childbearing potential must have a negative pregnancy test at screening and be willing to have additional pregnancy tests during the study and must agree to use adequate contraception during the study and for approximately 90 days following the last administration of investigational product to avoid pregnancy. Adequate contraception is defined as oral, intravaginal, transdermal, implantable or

injectable contraceptives, intrauterine devices, surgical sterilization (achieved through hysterectomy, oophorectomy, or bilateral salpingectomy or tubal ligation in addition to/or a combination of an intrauterine hormone-releasing system (IUS) and spermicid

Exclusion criteria

1. Certain disease subtypes or occurrences, as follows:
a. Cohort 1: APL, CML in blast crisis, iEMR.
b. Cohort 2: PMBCL, DLBCL transformed from diseases other than indolent NHL, Burkitt Lymphoma
c. Cohort 3: Active plasma cell leukemia, myeloma with amyloidosis, systemic light chain amyloidosis
d. Cohort 4: Known or suspected history of Richter*s transformation
2. WBC count > 50,000/ µL (uncontrollable with cytoreductive therapy) (Cohort 1 only).
3. Known central nervous involvement, as follows:
a. Cohort 1: Clinically active CNS leukemia. Previously controlled CNS leukemia is acceptable, however
b. Cohort 2: Active CNS lymphoma or meningeal involvement
c. Cohort 3: Active CNS MM
d. Cohort 4: Active CNS leukemia
4. Prior menin inhibitor therapy (exept for subjects in Cohort 1).
5. Known positive test for human immunodeficiency virus, hepatitis C, or hepatitis B surface antigen. Of note: HBV core Ab positive but HBV DNA negative subjects with no prior history of reactivation with prior CD20 monoclonal antibody exposure and prophylaxis would be allowed with reinstitution of appropriate prophylaxis; HCV Ab positive after treatment with anti-hepatitis C medications and viral load negative for at least 6 months would be eligible. If the subject is known to be cytomegalovirus (CMV) IgG or CMV IgM positive, the subject must be evaluated for the presence of CMV DNA by PCR. Subjects who are known to be CMV IgG or CMV IgM positive but who are CMV DNA negative by PCR are eligible. Antiviral prophylaxis should be considered per institutional protocol.
6. Subjects with a pre-existing disorder predisposing them to a serious or life-threatening infection (e.g., cystic fibrosis, congenital or acquired immunodeficiency, bleeding disorder, or cytopenias not related to acute leukemia, DLBCL, MM, or CLL/SLL).
7. An active uncontrolled acute or chronic systemic fungal, bacterial, or viral infection.
8. Significant cardiovascular disease including unstable angina pectoris, uncontrolled hypertension or arrhythmia, history of cerebrovascular accident including transient ischemic attack within 6 months prior to the first dose of the study treatment, congestive heart failure (New York Heart Association [NYHA] Class III or IV) related to primary cardiac disease, ischemic or severe valvular heart disease, or a myocardial infarction within 6 months prior to the

first dose of study treatment. Additional cardiovascular exclusions include any evidence of pericardial effusion or LVEF < 45% assessed by echocardiogram (ECHO), multi-gated acquisition (MUGA), or local standard.
9. Mean QTcF or QTcB of > 470 millisecond (ms) on triplicate ECGs performed within 5 minutes of each other.
10. Major surgery within 4 weeks prior to the first dose of study treatment. Surgery requiring local/epidural anesthesia (excluding biopsies) must be completed at least 72 hours before study drug administration and the subject should be recovered.
11. Unable to swallow tablets or have gastrointestinal disease or dysfunction that may interfere with oral absorption of study treatment, such as:
a. Chronic diarrhea or ingestion (e.g., short-gut syndrome, gastroparesis, etc.).
b. Cirrhosis with a Child-Pugh score of B or C.
c. Post gastrectomy
12. GVHD: Signs or symptoms of acute GVHD of any severity or chronic GVHD other than disease limited to skin that is adequately controlled with topical steroids alone within 3 weeks of enrollment. All transplant subjects must have been off all systemic immunosuppressive therapy and calcineurin inhibitors for at least 3 weeks prior to enrollment. The use of topical steroids for cutaneous GVHD is allowed and stable systemic steroid doses less than or equal to 20 mg of prednisone or equivalent daily is permitted with Medical Monitor approval.
13. Concurrent malignancy in the previous 2 years with the exception of adequately treated non-melanomatous skin cancer, or carcinoma in situ (e.g., breast carcinoma, cervical cancer in situ, melanoma in situ) treated with potentially curative therapy; superficial bladder cancer not treated with intravesical chemotherapy or BCG within 6 months, localized prostate cancer and PSA <1.0 mg/dL on 2 consecutive measurements at least 3 months apart with the most recent one being within 4 weeks of study entry. Concurrent malignancy must be in complete response or no evidence of disease during this timeframe.
14. Any underlying medical condition (including uncontrolled diabetes and muscular glycogenosis) that, in the Investigator*s opinion, will make the administration of study treatment hazardous or obscure the interpretation of toxicity determination or AEs.
15. Women who are pregnant or lactating. All female subjects with reproductive potential must have a negative pregnancy test prior to starting study treatment.
16. Known recent (within the past year) or ongoing alcohol or drug abuse.
17. Live, attenuated vaccine within 4 weeks before the first dose of study treatment.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-06-2023
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BMF-219
Generic name:	BMF-219

Ethics review

Approved WMO Date:	31-10-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-04-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-04-2023
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-11-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-12-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EU-CTR	CTIS2024-515744-23-00
EudraCT	EUCTR2022-002798-27-NL
ClinicalTrials.gov	NCT05153330
CCMO	NL82560.091.22