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A study testing two targeted medicines, bomedemstat, which helps normalise blood cell development, and momelotinib, which reduces symptoms and anaemia, to see whether the combination is safe and effective for people with myelofibrosis

Submission date 12/02/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 16/02/2026	**Overall study status** Ongoing	
Last Edited 16/02/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This is an open-label, single-arm, phase II interventional study designed to evaluate the safety and efficacy of bomedemstat (IMG-7289) when added to momelotinib in patients with myelofibrosis (MF) who exhibit a suboptimal response to momelotinib alone or who present with baseline cytopenias and do not achieve adequate improvement after 12 weeks of momelotinib monotherapy.

Who can participate?
Patients aged 18 years and over with MF.

What does the study involve?
The study consists of three phases:
1. Screening Phase (up to 28 days)
2. Momelotinib Monotherapy Phase — Weeks 0–12
3. Combination Treatment Phase (Momelotinib + Bomedemstat) — Weeks 12–24
4. Post-Treatment Follow-up Phase (30 days post last dose + long-term survival follow-up)
All patients will continue on Momelotinib throughout the study unless toxicity or safety considerations necessitate modification.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
United Lincolnshire Hospitals NHS Trust, UK.

When is the study starting and how long is it expected to run for?
November 2026 to November 2029.

Who is funding the study?
MSD Sharp and Dohme GmbH.

Who is the main contact?
Prof Ciro Rinaldi, crinaldi@lincoln.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Study to assess the safety and efficacy of bomedemstat (IMG-7289) in combination with momelotinib in patients with myelofibrosis

Study objectives
Myelofibrosis is a disease with heterogeneous driver pathways involving JAK-STAT activation, inflammatory cytokine signaling, and aberrant megakaryopoiesis. Momelotinib targets JAK1 /JAK2 and ACVR1, improving anemia and splenomegaly. However, a proportion of patients fail to achieve adequate spleen, symptom, or hematologic improvement.
Bomedemstat, an irreversible LSD1 inhibitor, may:
• Modify megakaryocyte function
• Reduce fibrosis
• Improve cytokine dysregulation
• Impact stem/progenitor dynamics
Sequential introduction of Bomedemstat at Week 12 allows assessment of Momelotinib’s initial stabilizing effect and evaluates whether LSD1 inhibition can rescue suboptimal responders without compromising hematologic tolerability.

Ethics approval required

Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Myelofibrosis

Interventions
Screening (≤ 28 days)

Momelotinib Alone (Weeks 0–12)
Week 12 Response Assessment
If Suboptimal Add Bomedemstat 50 mg QD

Combination Phase (Weeks 12–24)

Week 24 Primary Endpoint Assessment

Safety Follow-Up (30 days post last dose)

Long-Term Follow-Up (q12 weeks for 12 months)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Bomedemstat, momelotinib

Primary outcome(s)
1. spleen volume reduction ≥35% (SVR35) measured using MRI, or CT if patients cannot tolerate MRI, at week 24

Key secondary outcome(s))

Completion date
01/11/2029

Eligibility

Key inclusion criteria
1. Male or female participants ≥18 years of age on the day of signing informed consent.
2. Histologically confirmed diagnosis of:
2.1. Primary Myelofibrosis (PMF), or
2.2. Secondary MF following Polycythaemia Vera (post-PV MF), or
2.3. Secondary MF following Essential Thrombocythaemia (post-ET MF)
(as defined by WHO 2022 criteria)
3. Disease risk category:
3.1. Intermediate-2 or High-risk MF according to DIPSS.
4. Cohort assignment (Investigator-defined; permitted insertion):
4.1. Cohort 1 — Momelotinib-Experienced:
4.1.1. Receiving Momelotinib 200 mg QD for ≥12 weeks prior to Week 12 assessment
4.1.2. Demonstrates suboptimal response at Week 12
4.2. Cohort 2 — Cytopenic MF:
4.2.1. Baseline Hb <10 g/dL and/or platelets <100 × 10^9/L
4.2.2. Starting Momelotinib at Week 0
4.2.3. Demonstrates suboptimal response at Week 12

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
40

Key exclusion criteria

1. Medical Conditions
1.1. Known hypersensitivity to Bomedemstat or MAOIs
1.2. Clinically significant GI conditions affecting absorption
1.3. Increased bleeding risk
1.4. Hereditary bleeding disorders
1.5. Active or chronic bleeding within 8 weeks
1.6. Autoimmune bleeding disorders
1.7. Uncontrolled comorbidities
1.8. Active secondary malignancies (with exceptions)
1.9. HBV/HCV/HIV status not meeting template criteria
1.10. Receipt of prohibited medications within 14 days

2. Prohibited Prior Therapies
2.1. Prior treatment with Bomedemstat or other LSD1 inhibitors
2.2. MAOIs or strong CYP3A4 modifiers
2.3. All hematopoietic growth factors (G-CSF, GM-CSF, EPO, TPO mimetics)
2.4. Investigational treatments within 4 weeks
Investigator addition permitted:
2.5. Prior treatment with Momelotinib is allowed for Cohort 1 (required)
2.6. Prior treatment with Momelotinib is allowed for Cohort 2 (not required)
2.7. Prior exposure to other JAK inhibitors (e.g., ruxolitinib, fedratinib) is allowed unless associated with severe toxicity

3. Prohibited During Study
(Verbatim text from first file retained)
3.1. MAOIs
3.2. Strong inhibitors/inducers of CYP3A4
3.3. Anticoagulants/antiplatelets/NSAIDs when platelets <100 ×10⁹/L

Date of first enrolment
01/11/2026

Date of final enrolment
01/11/2028

Locations

Countries of recruitment
United Kingdom

England

France

Spain

United Arab Emirates

United States of America

Study participating centre
United Lincolnshire Teaching Hospitals NHS Trust
Lincoln County Hospital
Greetwell Road
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England
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Sponsor information

Organisation
United Lincolnshire Hospitals NHS Trust

ROR
https://ror.org/0377kyv52

Funder(s)

Funder type

Funder Name
MSD Sharp and Dohme

Alternative Name(s)
MSD Sharp & Dohme, MSD Germany, MSD Sharp & Dohme GmbH, MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available