

# 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

<b>Submission date</b> 12/02/2026	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/02/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/02/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

### Contact name

Prof Ciro Rinaldi

### Contact details

Lincoln County Hospital  
Greetwell Road  
Lincoln  
United Kingdom  
LN2 5QY  
+44 07720373877  
crinaldi@nhs.net

## 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)**

Not yet submitted

**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 ( $\leq 28$  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  $\geq 35\%$  (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  $\geq 18$  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  $\geq 12$  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  $< 100 \times 10^9/L$
    - 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  $<100 \times 10^9/L$

## 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  
Lincoln  
England  
LN2 5QY

## 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

