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A healthy volunteer study of MOS-118 nasal spray

Submission date
24/07/2025

Recruitment status
No longer recruiting

Registration date
24/07/2025

Overall study status
Completed

Last Edited
01/06/2026

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea is a condition in which the throat muscles partially or completely collapse during sleep, resulting in multiple episodes of disturbed breathing and snoring throughout the night. This causes periodic episodes of low oxygen levels, poor quality sleep and excessive daytime sleepiness. There are currently no medications that can be used to successfully treat obstructive sleep apnoea.

Mosanna Therapeutics has developed a nasal spray to treat obstructive sleep apnoea. The intended mechanism is to temporarily alter the behaviour of the muscles of the throat and upper airways, reducing their tendency to collapse during sleep. This study aims to assess how well the spray is tolerated and its safety; where the spray is distributed within the nose and throat after administration; and how long it is retained in the nasal and pharyngeal tissues. The study will also aim to assess how much of the drug within the spray is absorbed into the blood.

Who can participate?
Healthy adult volunteers aged 18 to 65 years. Both men and women can participate.

What does the study involve?
For each participant, the study will consist of a screening visit, 5 treatment visits and a follow-up visit. For 4 of the treatment visits, participants will remain at the study site overnight, for approximately 26 hours. Participation will last approximately 10 weeks in total.

During the study, 5 different treatments will be given to each participant:

Treatment (formulation) 1: Placebo - 1 spray/nostril (no active drug)

Treatment (formulation) 2: MOS-118 - 1 spray of 9mg/nostril (18 mg)

Treatment (formulation) 3: MOS-118 - 1 spray of 9mg/nostril (18 mg)

Treatment (formulation) 4: MOS-118 - 1 spray of 9mg/nostril (18 mg)

Treatment (formulation) 5: MOS-118 - 1 spray of 9 mg/nostril (18 mg)

The dose of active drug in each spray is the same for Treatments 2, 3, 4, and 5. These 4 formulations vary in terms of drug particle size and the solutions used to deliver the drug. To monitor how the spray behaves in the nasal cavity after being administered, a small amount of radiation will be added to each of the 4 formulations containing the active drug (Treatments 2-5). The radiation emitted will be detected by taking images using a gamma camera.

Blood samples will be taken at all treatment visits to assess the amount of the medication which is absorbed into the body/bloodstream.

What are the possible benefits and risks of participating?
There are no direct benefits to participants taking part in this study other than receiving physical examinations and obtaining information about their general health. The results obtained could be important for the development of medicinal products which may benefit others. Participants will receive a small exposure to radiation. The radiation dose is low and similar to that used in routine medical imaging procedures.

Where is the study run from?
BDD Pharma

When is the study starting and how long is it expected to run for?
June 2025 to August 2025.

Who is funding the study?
Mosanna Therapeutics

Who is the main contact?
Dr Lyn Corry, Lyn.Corry@bddpharma.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Lyn Corry

ORCID ID
https://orcid.org/0009-0008-4224-4667

Contact details
BDD Pharma Ltd
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF
0141 552 8791
Lyn.Corry@bddpharma.com

Additional identifiers

Integrated Research Application System (IRAS)
1009022

Phase I trial BDD code
BDD22320

Protocol serial number
MOS118-101

Study information

Scientific Title
An open-label, placebo-controlled, cross-over, pharmacoscintigraphic and PK study testing MOS-118 nasal spray in healthy volunteers

Study objectives
To evaluate the safety and tolerability, plasma pharmacokinetics and behaviour (via scintigraphy) of 4 different formulations of a single dose of MOS-118 via nasal administration relative to placebo in healthy adult participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/03/2024, London - Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048128; brent.rec@hra.nhs.uk), ref: 24/LO/0003

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Crossover

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
This is a pharmacoscintigraphic open-label crossover study.

Treatment 1 (Placebo): 2 administrations of 100 µL (one spray in each nostril of one of the diluents used in active treatment)

Treatment 2 (MOS-118 (SU2810)): 2 administrations of 9 mg in 100 µL (one spray in each nostril)

Treatment 3 (MOS-118 (SU4110)): 2 administrations of 9 mg in 100 µL (one spray in each nostril)

Treatment 4 (MOS-118 (SU4130)): 2 administrations of 9 mg in 100 µL (one spray in each nostril)

Treatment 5 (MOS-118 (SU4510)): 2 administrations of 9 mg in 100 µL (one spray in each nostril)

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
MOS-118

Primary outcome(s)
1. Safety and tolerability: Treatment-emergent adverse events measured using data collected on the incidence, type, timing, severity and relatedness of treatment-emergent adverse events at data assessment

2. Safety and tolerability: Safety bloods measured using standard blood testing methods at baseline, 24 hours post each dose, and follow-up visit

3. Safety and tolerability: Urine measured using standard urinalysis methods at baseline and at follow-up visit

4. Safety and tolerability: Heart assessment measured using 12-lead ECG at baseline, pre-determined timepoints post-dose and at follow-up visit

5. Safety and tolerability: Vital signs assessment measured using standard methods at baseline, pre-determined timepoints post-dose and at follow-up visit

6. Safety and tolerability: Clinically significant change in physical examination measured using standard methods at screening, treatment visit and follow-up visit

Key secondary outcome(s)
1. Location and residence time within the nasal cavity of MOS-118 measured using scintigraphic imaging at timepoints over 10 hours post-dose

2. Pharmacokinetic parameters of MOS-118 measured using samples taken for bioanalysis at pre-determined timepoints up to 24 hours post-dose

Completion date
20/08/2025

Eligibility

Key inclusion criteria
1. Age: Males and females, aged between 18 and 65 years inclusive
2. Weight & Body mass index (BMI): BMI between 18.0 and 32.0 kg/m², inclusive, and a body weight ≥ 50 kg
3. Compliance: Understands and is willing, able, and likely to comply with all study procedures and restrictions
4. Consent: Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent (signed and dated) obtained before any trial-related activities.
5. General health: Healthy (as determined by the Investigator) based upon the results of a medical history, physical examination (including nasal exam), vital signs, 12-lead ECG and clinical laboratory safety tests
6. Administration of Nasal Spray: Demonstrates ability to use nasal administration device at screening visit as assessed by investigator
7. Family Planning/Contraception:
7.1. Male Participants: Male participants are eligible to participate if they agree to the following during the study intervention period and for at least 90 days after the last dose of study intervention:
7.1.1. Refrain from donating sperm PLUS, either:
7.1.2. Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent OR
7.1.3. Must agree to use a male condom alongside female partner use of an additional highly effective contraceptive method with a failure rate of < 1% when having sexual intercourse with a woman of childbearing potential who is not currently pregnant
7.2. Female Participants: A female participant is eligible to participate if she is not pregnant or breastfeeding, and one of the following conditions applies:
7.2.1. Is a woman of non-childbearing potential (WONCBP) OR
7.2.2. Is a WOCBP and using a contraceptive method that is highly effective (with a failure rate of < 1% per year), with low user dependency during the study intervention period and at least until the follow-up visit of the study
7.2.3. Female participants must refrain from egg donation during the study intervention period and at least until the follow-up visit of the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit

18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
8

Key exclusion criteria
1. Medical History:
1.1. Current or recurrent disease/condition that, in the opinion of the investigator, could affect study conduct; the safety of the participant because of participation; and/or the ability of the participant to complete the study or laboratory assessments (including but not exclusively a history of hay fever, rhinitis, asthma, syncope or hypertension)
1.2. Current or relevant previous history of severe or unstable psychiatric illness, that may require treatment or make the participant unlikely to fully complete the study, or that presents undue risk from the study medication or procedures
1.3. Having any illness (e.g., active allergy, fever, hypersensitivity reaction) judged by the investigator as clinically significant in the 3 months prior to first dosing of MOS-118
1.4. Haematological or biochemical blood test at screening outside normal ranges and deemed clinically significant by the PI or medically qualified designee
1.5. Clinically significant physical examination or clinically significant investigations (including those performed at screening and during treatment arm), deemed by the investigator to render the volunteer unfit for the study
1.6. Measured body temperature >38°C (at screening or dosing visit)
1.7. Any history of the following:
1.7.1. Rhinitis (on or off therapy) and/or stuffy nose in the 2 weeks prior to first dosing
1.7.2. Nasal surgery within 3 months of first dosing
1.7.3. Nasal obstruction impacting delivery
1.7.4. Active chronic sinusitis
1.7.5. Nasal polyps requiring surgical intervention
1.7.6. Significant septal deviation
1.7.7. Active nasal or sinus infection or mucosal inflammation
1.7.8. History of asthma or chronic rhinitis as an adult
1.7.9. Anatomical abnormalities requiring surgery which may impact intranasal delivery
1.8. Positive serology suggestive of acute or chronic infection with Human Immunodeficiency Virus (HIV), Hepatitis B (Hep B) (HBsAg positive) or Hepatitis C Virus (HCV)
1.9. History of hepatitis from any cause, except for hepatitis A, that was resolved within 3 months prior to first dose of MOS-118
1.10. History of significant cardiac pathology or clinically significant abnormality on ECG, in the opinion of the investigator, or corrected QT interval (as calculated by Fridericia formula) on 12-lead ECG as defined by QTc ≥ 450 (females) and 430 (males) msec
2. Medications
2.1. Use of nasal sprays, rinses or douches in the 2 weeks prior to first and/or any subsequent dose of MOS-118
2.2. Participant is scheduled to take prescribed medication within 14 days (or 5 half-lives – whichever is longer) prior to the first dose of MOS-118 which, in the opinion of the investigator, will interfere with the study procedures or compromise safety

2.3. Participant is scheduled to take over-the-counter (OTC) medication, including vitamins, pro and prebiotics and natural or herbal remedies, within 48 hours prior to the first dose of MOS-118 unless approved by the investigator

3. Alcohol/Substance Abuse
3.1. Recent history (within the last year) of alcohol or other substance abuse
3.2. Previous regular/habitual use of inhaled recreational drugs
3.3. Participants have an average weekly alcohol intake of greater than 14 units
3.4. Participant has a positive urine drugs of abuse test at screening or prior to dosing evaluation
3.5. Participant has a positive breath alcohol test at screening or prior to dosing evaluation (breath testing may be repeated once at investigator discretion within a 5-minute window of first test)
4. Smoking
4.1. Participants have recently discontinued smoking or vaping (less than 3 months)
4.2. Participant is currently a smoker, vaper or user of nicotine-containing products
4.3. Participant has a positive urine cotinine test at screening or prior to dosing evaluation
5. Allergy/Intolerance
5.1. Participant has a history of allergy to any component of the dosage form or any other allergy, which, in the opinion of the PI or medically qualified designee responsible, contraindicates their participation.
6. Clinical Studies
6.1. Participation in another clinical study (including the final post-study examination) of an investigational drug within the 12 weeks before screening visit, or five elimination half-lives of the previous study drug, whichever is longer
6.2. Participant whose participation in this study will result in a participation in more than four studies over a twelve-month period
7. Personnel
7.1. An employee of the Sponsor, or study site or members of their immediate family
8. Radiation Exposure
8.1. Participant has a total dosimetry value which, in the opinion of the PI or medically qualified designee/physician responsible, contraindicates their participation
9. Family Planning
9.1. Male participants who are intending to father a child during or in the 90 days following the study or are unwilling or unable to follow the precautions outlined in inclusion criterion 7
9.2. Female participants who are intending to conceive a child during the study or unwilling /unable to follow the precautions outlined in inclusion criterion 7
9.3. Female participants who are currently pregnant
10. Blood
10.1. Blood donation or significant blood loss within 3 months of screening and for the duration of the study
10.2. Difficulty accessing veins for cannulation or blood sampling
11. Breastfeeding
11.1. Female participants who are breastfeeding or expressing milk for human consumption
12. Other
12.1. Participant has any non-removable metal objects such as metal plates, screws etc in their face or head, which in the opinion of the PI or medically qualified designee could affect the study conduct/imaging
12.2. Participant with high levels of physical activity (e.g., competitive athletes or those engaging in intense daily workouts)

Date of first enrolment

09/06/2025

Date of final enrolment
23/06/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
BDD Pharma Ltd
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Sponsor information

Organisation
Mosanna Therapeutics

Funder(s)

Funder type
Industry

Funder Name
Mosanna Therapeutics

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			01/06/2026	No	No