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CPU520– anticoagulant JNJ-70033093

We are currently recruiting healthy male/female volunteers between the age of 18 and 55 (inclusive) to participate in a study for the evaluation of acceptability profile of different milvexian oral dispersions.

Please note that you are eligible for this study only if you are not currently participating in any other study, either in Johnson & Johnson CPU or any other research center. This will be verified through an international database called Verified Clinical Trials (VCT).

A randomized, crossover study in healthy adult participants to evaluate the oral bioavailability of a milvexian pediatric tablet formulation relative to an adult tablet formulation (Part 1), the effect of concomitant food intake on the oral bioavailability of a milvexian pediatric tablet formulation (Part 2), and the acceptability profile of different milvexian oral dispersions (Part 3)

The objectives of part 3 of this study is to evaluate the effect of sweetener and/or flavoring agents on the overall acceptability (including taste) of milvexian administered as oral dispersions in healthy adult participants.

It is preferable to register online through our website www.cpu.be or via e-mail to cpu@its.jnj.com.

When registering, please provide us the following information:
- Name and First name
- Telephone number
- SID - personal volunteer number, if known
- Study number (= CPU520)
- The cohort you wish to participate in

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Study process

After formal approval by the Ethics Committee, Johnson & Johnson CPU conducts the study starting from March 2025. The study consists of 2 cohorts (groups) with a total of 9 participants.

The following visits take place:

- Initial screening visit
  - You will read the informed consent form (ICF). To prepare, you will receive this document via e-mail prior to the screening.
  - Next, you will have a conversation with a physician, and you can ask questions. If you wish to participate in the study, you and the physician will sign the form.
  - The physician will review your medical history and medication use. Depending on the study, other additional examinations may take place, such as [physical examination, weight measurement, blood pressure, temperature, heart monitoring, blood and urine tests, pregnancy test, alcohol and/or drug test, or other tests.

- Possible follow-up visits
  - Additional examinations may be scheduled throughout the study, such as additional blood tests or a visit for specialized examination. These tests and/or examinations are always done by appointment. Retesting (verification of abnormal screening results) will be conducted within +/- 7 days after screening, by appointment.

- 3 Ambulatory visits
  - These visits take place by appointment from the morning until the afternoon.

- 1 Follow-up visit (the last visit)
  - You will undergo a final examination to check your health status one last time. This marks the end of your participation in the study.

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Admission requirements

You may be eligible for a screening visit if you meet the following requirements:

General requirements:

Sex	**Male or Female**
Age	**Between 18 and 55 years (inclusive)**
BMI	**Between 18 and 30 kg/m2** (calculate your BMI on cpu.be)
Body Weight	**More than 50 kg**

Study specific requirements:

Informed consent form (ICF)	Willing to sign an informed consent form and follow the study restrictions.
Medication history	14 days before the screening, do not use prescription or over-the-counter medications (including vitamins, herbal supplements, etc.) until the end of the study. Allowed: contraception, hormone replacement therapy
Medical history	General health; you have no (medical history) of the following diseases: • Congenital abnormalities. • Cardiovascular diseases, including lipid disorders. • Respiratory diseases. • Gastrointestinal disorders. • Kidney diseases, bladder-urinary tract diseases. • Metabolic diseases such as diabetes, thyroid problems. • Infectious diseases: such as hepatitis B or C, HIV, tuberculosis. • Blood disorders. • Neurological conditions. • Skin diseases. • Diseases of the musculoskeletal system: muscles/bones.

	• Psychiatric diseases. • Cancer: skin, breast, lung, uterus. • Other relevant diseases.
Allergies	You do not have any immune system reactions to foreign substances (such as certain medications or food).
Surgery	Not allowed from screening and until the last administration of the study medication.
Gastric reduction	Volunteers with gastric reduction (e.g. Gastric bypass, gastric ring etc.) are not allowed.
Easy access to veins	Blood collections should go smoothly in both arms.
Donations	Eggs: Not allowed during the study and up to 34 days after the study.
Participation in other studies	Not allowed: • From 90 days before the first dose; to 2 months after the last follow-up • Previously participated in part 1 or part 2 of this study
J&J employee	No employee or family member of Johnson & Johnson staff is allowed to participate.

Requirements regarding contraception and reproduction:

- **Women - meet the following requirements:**

Either: Postmenopausal	If you have not had a period for more than 12 month. Additional blood tests can provide further clarification about your menopausal status.
Either: Sterilized	After the removal of ovaries and/or uterus, the fallopian tubes are clamped or blocked. Please bring proof of the procedure during the screening.
Either: Effective method of contraception	During the study and for at least 34 days after the last dose of the study medication*:* • Oral, intravaginal, transdermal hormonal contraception • Contraceptive injection

	• Intrauterine devices • Hormone-releasing Intrauterine device • Contraceptive implants • Sterilized partner • Sexual abstinence
Not be pregnant and/or become pregnant	During the study
No breastfeeding	During the study
Condom	The male partner should use a condom, even if sterilized.

- **Men – meet the following requirements:**

Condom	You must use a condom, even if sterilized.
Contraception	The female partner should use an acceptable form of contraception such as the pill, an intrauterine device, surgical sterilization, etc.

Requirements regarding lifestyle:

Smoking	Do not use nicotine-containing substances (such as cigars, nicotine patches, or e-cigarettes) from 6 months before the screening and do not smoke until the end of the study. Avoid smokey environments, BBQs, and charcoal fires.

Alcohol and drugs	No alcohol or drugs from [24 days before taking the study medication of each period. There is no history or current evidence of alcohol or drug abuse.
Dietary Restrictions	No food products containing poppy seeds should be consumed from 72 hours before screening and 72 hours before entering the unit until the end of the last visit of each study period. No extensive amounts of tea or coffee (5 cups a day) or 8 glasses of cola during the whole study.
Strenuous physical exercise	**From 72 hours before entry, and during your stay at the unit, as well as 72 hours prior to each visit to the CPU**, activities such as jogging, weightlifting, or any activity that you are not accustomed to and that results in muscle fatigue, are not permitted.
Meals during your stay	We serve standard meals in the unit and you are expected to be willing to consume them. Non-vegetarian meals may contain (pork) meat. The meals on day 1 must be completely consumed. The breakfast does contain a fixed amount of non fatty products. For vegetarians, an alternative can be provided. Please indicate this during the screening.

Selection process for participation in the study

The main research physician determines based on your screening results whether you qualify for the study. After the screening, you will be contacted by phone to inform you of the results.

Do you not meet the study requirements?

- The (main) research physician will call you to explain why you cannot participate in the study.

Do you meet the study requirements?

- A random selection through an automatic computer system will determine whether you are invited as an effective, reserve, or standby participant.

Were you selected as an effective participant?

- You will come in according to the schedule.
- On the day of arrival, it will be checked whether you still meet the study requirements. If it turns out that you no longer meet the study requirements, you cannot participate in the study and you will go home.

Were you selected as a reserve participant?

- You will come in according to the schedule.
- On the day of arrival, it will be checked whether you still meet the study requirements. If it turns out that you no longer meet the study requirements, you cannot participate in the study, and you will go home.
- If an effective participant drops out, there is a chance that you will fill in. Keep in mind that you must be available for the entire study schedule.
- If you remain as a reserve, you may leave the unit after the first dose.

Study compensation

You will receive a compensation for your invested time and commitment.

- € 55 for the screening
- € 500 (including screening compensation) for the full study, including reimbursement for study-related expenses, including any contraception costs
- €55 for each period as reserve

For each visit, including additional visits for extra tests, you will receive a mileage reimbursement set at € 0.43 per kilometer. We reimburse a minimum of 24 kilometers and a maximum of 100 kilometers for each one-way trip.

No compensation will be paid if you test positive for drugs or alcohol during the screening.

If you decide to stop the study early, the principal investigator of the study will determine the compensation based on the hours you have invested. You will receive a pro rata compensation, calculated according to the study protocol.

The payment for standby participants, reserves, and non-selected participants after the screening will begin after the first dosing day of the study cohort. The payment for effective participants starts after the final follow-up. We have a payment term of +/- 6 to 8 weeks. Please inform the recruitment department in a timely manner of any changes to your bank account number to ensure a smooth payment process.

Both the study calendar and the compensation are subject to change, depending on the protocol and/or decision of the Ethics Committee.

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How to register?

It is preferable to register online through our website www.cpu.be or via email to cpu@its.jnj.com.

If you register yourself, please provide us with the following information:

- Name and First name
- Phone number
- SID - personal volunteer number, if known
- Study number (= CPUXXX)
- The cohort you wish to participate in

During office hours (08:00 AM - 05:00 PM), you can also register by phone at 0800 97 886 or +32(0)3 640 32 30.

Your response to this recruitment letter only indicates your interest in obtaining information and does not guarantee participation in the study.


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