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CPU529 – Immunological disorders

We are currently recruiting healthy male and female volunteers between the age of 18 and 60 (inclusive) to participate in a study involving study medication for the treatment of immunological disorders.

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 single-dose, open-label, randomized, multipart crossover study to Assess the PK and Food Effect of an Icotrokinra Adult Tablet Formulation and to Assess the PK of an Icotrokinra Pediatric Tablet Formulation

The objectives of this study are:

Part 1:

- Evaluate how long Icotrokinra stays in and act on the body (this is called pharmacokinetics) when it is given as different tablet formulations under different food conditions.
- Another purpose of this part of the trial is to find out if side effects are different when taking the different formulations under different food conditions. Side effects are unexpected, unwanted, and sometimes unpleasant, reactions from taking a drug.

Part 2:

- Evaluate how long Icotrokinra stays in and act on the body (this is called pharmacokinetics) when it is given as different tablet formulations under different ways of administration.
- Another purpose of this part of the trial is to find out if side effects are different when taking the different formulations under different ways of administration. Side effects are unexpected, unwanted, and sometimes unpleasant, reactions from taking a drug.
- The acceptability of the formulations will be assessed using a questionnaire.

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 (= CPU529)
- 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 June 2025. The study consists of 2 parts with a total of 32 participants (part 1: 16 participants/ part 2: 16 participants).

The following visits take place:

- 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 (if applicable), alcohol and/or drug test, tuberculosis test, cotinine 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.

- 4 Stays
  - 4 days, 3 nights
  - Leaving the unit and receiving visitors during the stay is not allowed

- 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/Female**
Age	**Between 18 and 60 years (inclusive)**
BMI	**Between 18.0 and 30.0 kg/m^2** (calculate your BMI on cpu.be)
Body Weight	**At least 50.0 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, dietary supplements, 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: • Cardiovascular diseases, including lipid disorders. • Respiratory diseases. • Gastrointestinal disorders. • Kidney diseases, bladder-urinary tract diseases. • Liver diseases • Metabolic diseases such as diabetes, thyroid problems. • Infectious diseases: such as hepatitis B or C, HIV, tuberculosis. • Blood disorders. • Neurological conditions. • Psychiatric diseases. • Cancer: skin, breast, lung, uterus. • Other relevant diseases.

Covid-19	You have a negative COVID-test on admission to the study site in each study period.
Allergies	You do not have any immune system reactions to foreign substances (such as certain medications or food). You have no known allergies, hypersensitivity, or intolerance to the studymedication.
Surgery	No major surgery allowed from 3 months before screening until 12 weeks after the last dose of the study medication. Participants with planned surgical procedures to be conducted under local anaesthesia may participate if the procedure is planned outside the CPU stay period and if it fits into the study planning. Please discuss this with the study physician first.
Gastric reduction	Volunteers with gastric reduction (e.g. Gastric bypass, gastric ring etc.) are not allowed.
Donations	• Blood or blood products: Not allowed from 3 months before the first dose of the study medication (more than 450 ml) until 90 days after the study. • Sperm: Not allowed during and until 90 days after the study. • Eggs: Not allowed during and until 90 days after the study.
Participation in other studies	Attention: It is not possible to participate in part 2 of this study if you have already been dosed in part 1 of this study. Furthermore, participation in other studies is also not allowed: • From 30 days before screening to 1 month after study completion OR • 5x the half-life of the investigational medication taken in a previous study. (Note: the longest period applies)
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 months. 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 90 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 and up to 90 days after the study.
No breastfeeding	During and up to 90 days after the study.
Condom	The male partner should use a condom.

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

Condom	You must use a condom.
Contraception	The female partner should use an acceptable form of contraception such as the pill, an intrauterine device, surgical sterilization, etc.
Not father a child	During the study and up to 90 days after the last study medication.

Requirements regarding lifestyle:

Smoking	No use of any tobacco products within 6 months prior to screening. Do not use nicotine-containing substances (such as cigars, nicotine patches, cigarettes, e-cigarettes, vapes, chewing tobacco or gum) during and until after completion of the study. Avoid smokey environments, BBQs, and charcoal fires.
Alcohol and drugs	No alcohol from 24 hours before taking the study medication until after the last blood collection in each study period. There is no history or current evidence of alcohol or drug abuse and you have a negative alcohol-drug test on admission to the study site in each study period.
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 products containing methylxanthines (e.g. chocolate, coffee, tea, or cola) 24 hours before administration of the study medication and during the stay at CPU. • Avoid excessive use of caffeine (ie, no more than approximately 500 mg/day, as contained in 5 ups of tea or coffee or 8 cans of cola) from screening and during the entire study. Caffeinated drinks are not allowed from 24 hours before administration of the study medication and during confinement in each treatment period. • Fasting from all food and drinks (except water) for at least 4 hours before blood collection and for at least 10 hours before administration of the study medication.
Strenuous physical exercise	**From 48 hours before entry, and during your stay at the unit, as well as 48 <u>hours prior to each visit to the CPU</u>**, 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 breakfast contains a fixed amount of fatty products if you receive treatment C or D. If you receive a high-fat breakfast, the meal must be consumed in its entirety. 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.

Were you selected as a standby participant?

- You will come in on the day of arrival.
- If a 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 fill in, 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 you are not selected as an effective or reserve participant, you may leave the unit after a maximum of 2 hours.

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Study compensation

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

- € 55 for the screening
- € 4310 (including screening compensation) for the full study, including reimbursement for study-related expenses, including any contraception costs
- € 293 (including screening compensation) for the reserve
- € 150 (including screening compensation) for the standby

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 (= CPU529)
- 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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