AbbVie Clinical Pharmacology Research Unit Information Sheet

The health and safety of volunteers and employees is our priority. We have safety protocols in place to keep the unit as safe as possible.

Buffalo
Check In: No Confinement

Study drug and design:

AbbVie is testing an investigational drug, which is not approved by the Food and Drug Administration (FDA) or any health authority, and is not currently available on the market. The objective of this study is to evaluate safety and characterize SC injection or infusion tolerability associated with administration of human immunoglobulin (10% solution) with or without study drug in healthy subjects at different volumes and injection/infusion rates.

Minimum Subject Selection Criteria:

YOU *may be eligible to take part in this clinical study if you meet the following conditions:*

- Healthy men and women 18-65 years old.
- Average weight for height (BMI 18 to 32).
- Females must be permanently surgically sterile or postmenopausal for 1 year.
- No history of any drug sensitivity or allergy.
- No presence of anything in the intended injection/infusion site area that would be contraindicated for study treatment administration (e.g., severe dermatitis, anatomical abnormality, tattoos, jewelry, or clothing that cannot be removed which obscures or interferes with the target area(s) of interest).
- No current or relevant history of hypercoagulable conditions (e.g., Protein C, Protein S, and antithrombin III deficiency), venous or arterial thrombotic/thromboembolic events.
- Has not received or is planning an elective procedure, invasive and non-invasive abdominal procedures including body contouring treatments (e.g., liposuction, cryolipolysis), tanning session, tattoo, or piercing within 30 days prior to study treatment administration or within 30 days after the last dose of study treatment.
- Has not received any treatment by injection within 30 days.
- No current or clinically significant history of chronic pain condition (e.g., fibromyalgia).
- No history of hyperprolinemia Type I or II.
- No current clinically significant known risk factors for renal dysfunction.
- Has not been treated with any investigational treatment or device within 30 days.
- No history of trypanophobia (the extreme and irrational fear of medical procedures involving needles).
- No history of drug or alcohol abuse within the last six months.
- No use of tobacco- or nicotine- containing products within 90 days prior to the first dose of study treatment.
- No history of any clinically significant illness/infection/major febrile illness, hospitalization, or any surgical procedure within 30 days prior to the first dose of study treatment.

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Screening at ACPRU in Grayslake

Screening dates: *(To find out if you are suitable to take part in this clinical study)*

- Next screening 24, 25, 31 August 01, 28, 29 September, and 05, 06 October 2026
- **Additional screening dates may be available**.
- Screening appointments are between the hours of 10:00am and 12:00 am and take approximately 3.5 hours.

Stipend:

- **Screening:** $300 (No compensation if urine drug/alcohol/cotinine screen is positive or if BMI is out of range.)
- **Study:** Compensation of up to $2,100 may be provided if selected and you complete the study.

Study dates: *(Please note that these dates and times are subject to change)*

Must complete all periods and/or follow up visit(s).

Note: There is no confinement in this study. You will have two clinic visits approximately 1- 2 days apart in the September group or the October group. You will have one follow-up telephone call approximately 30 days after your last treatment.

Please call our recruiting office at 1-800-827-2778 to schedule an appointment.