

A Phase 1, Single-Center, Open-label, Infusion Dose Optimization Study of ABP-700 in Healthy, Adult Subjects

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To assess the safety and tolerability of intravenous (IV) infusion doses and infusion dosing methodologies of ABP-700 alone or in the presence of pre-medications commonly used in the monitored anesthesia care (MAC) setting

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26835

Bron

NTR

Aandoening

Monitored anesthesia care (MAC) and/or general anesthesia.

Ondersteuning

Primaire sponsor: The Medicines Company, University Medical Center Groningen (UMCG)

Overige ondersteuning: The Medicines Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the safety and tolerability of intravenous (IV) infusion doses and infusion dosing methodologies of ABP-700 alone or in the presence of pre-medications commonly used in the monitored anesthesia care (MAC) setting.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: The highly dynamic nature of surgical and procedural intervention, as well as the short duration of these procedures, demands the development of potent yet rapidly reversible anesthetic agents. Ideally, the pharmacokinetics (PK) and pharmacodynamics (PD) of these anesthetic agents should be better matched to the procedures being performed. ABP-700 is a newly developed, potent, positive allosteric modulator of the GABAA receptor. Its mechanism of action is via potentiation of GABAA receptor activation produces its sedative and anesthetic effects. ABP-700 contains an ester bond that was precisely designed to undergo rapid hydrolysis in the body by nonspecific tissue esterases that produce an inactive carboxylic acid metabolite.

Purpose: to assess the safety and tolerability of infusion doses and methodologies of ABP-700 alone or in the presence of pre-medications, to induce and maintain anesthesia.

Design: this is an open-label, single-center infusion dose study. Up to 20 cohorts of 4 subjects are planned. Each cohort will be assigned a specific dosing regimen. Safety will be monitored and the level of sedation/anesthesia will be assessed throughout the study. After each cohort, the PI and sponsor will evaluate all available data relevant to the safety, tolerability, and PD data in order to repeat, expand or discontinue a dosing regimen.

Doel van het onderzoek

To assess the safety and tolerability of intravenous (IV) infusion doses and infusion dosing methodologies of ABP-700 alone or in the presence of pre-medications commonly used in the monitored anesthesia care (MAC) setting

Onderzoeksopzet

Day 1, 2 and 5.

Onderzoeksproduct en/of interventie

ABP-700

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy, adult, men and women, 18-55 years of age, inclusive.
2. Subject must give written informed consent before initiation of any study-related procedures.
3. Continuous non-smoker who has not used nicotine-containing products for at least 6 months prior to the first dose.
4. Body Mass Index (BMI) ≥ 17.5 and ≤ 30.0 kg/m², and a total body weight >50 kg, at screening and check-in.
5. Medically healthy with no clinically significant out of range laboratory findings, vital signs or ECGs, as deemed by the PI.
6. Women of non-childbearing potential, i.e., must have undergone one of the following sterilization procedures at least 6 months prior to the first dose:
 - a. hysteroscopic sterilization;
 - b. bilateral tubal ligation or bilateral salpingectomy;

c. hysterectomy;

d. bilateral oophorectomy;

or be postmenopausal with amenorrhea for at least 1 year prior to the first dose and FSH serum levels consistent with postmenopausal status (greater than 30 IU/L).

7. Women of child bearing potential must agree to use one or more of the following forms of contraception from the time of signing the informed consent form through 90 days following the last administration of study medication: hormonal (i.e., oral, transdermal, implant, or injection); double barrier (i.e., condom, diaphragm with spermicide); intrauterine device (IUD); vasectomized partner (six months minimum); or abstinence.

8. Non-vasectomized men must agree to use a condom with spermicide or abstain from sexual intercourse during the study until 90 days beyond the last dose of study medication. Men who have been vasectomized less than 4 months prior to study start must follow the same restrictions as non-vasectomized men.

9. Men must agree not to donate sperm from the first dose until 90 days after dosing.

10. Obtain a score of I or II using the Modified Mallampati Scoring.

11. Understand the study procedures in the informed consent form(s) (ICF(s)), and be willing and able to comply with the protocol.

12. Agree not to make any public disclosure of personal medical data related to the study or other information related to the study, including posting on any website or social media site (e.g., Facebook, Twitter, etc.).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History or presence of significant cardiovascular disease, or cardiovascular disease risk factors, hyperlipidemia, coronary artery disease, or any known genetic pre disposition to cardiac arrhythmia (including long QT syndrome).

2. History or presence of significant pulmonary, hepatic, renal, hematological, gastrointestinal, endocrine, immunologic, dermatologic, neurological (inclusive of any seizure disorder), or psychiatric disease.

3. History of any illness that, in the opinion of the PI, might confound the results of the study or pose an additional risk to the subject by their participation in the study.

4. Surgery within the past 90 days prior to dosing judged by the PI to be clinically relevant.

5. History of febrile illness within 5 days prior to dosing.

6. History or presence of alcoholism, drug abuse or illicit drug use within the past 2 years.
7. History of regular alcohol consumption exceeding 7 drinks/week for women or 14 drinks/week for men [1 drink = 5 ounces (150 mL) of wine or 12 ounces (360 mL) of beer or 1.5 ounces (45 mL) of hard liquor] within 6 months of screening.
8. Hypersensitivity or idiosyncratic reaction to components of ABP-700 (meglumine and/or sulfobutylether-beta-cyclodextrin), fentanyl, sufentanil, remifentanyl, midazolam, egg, egg products, soybeans, soy, or to compounds related to the study medications.
9. Women who are pregnant or lactating.
10. Positive results for the urine drug screen and alcohol breath test at screening or check-in (Day -1).
11. Positive urine cotinine at screening.
12. Positive results at screening for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg), or hepatitis C antibodies (HCV).
13. Single 12-lead ECG demonstrating QTcF interval >450 msec at screening and/or Day -1.
14. Unable to refrain from or anticipates the use of any drug, including prescription and non-prescription medications, herbal remedies, or vitamin supplements beginning approximately 14 days prior to dosing and throughout the study, with the exception of oral contraceptives. Ibuprofen (1.2 g per 24 hour period) may be permitted during the study at the PI's discretion.
15. Use of any drugs known to be hormonal replacement therapy, inducers of cytochrome P450 (CYP) enzymes, including St. John's Wort, within 28 days prior to the first dose of study medication. Appropriate sources will be consulted by the PI to confirm lack of PK/PD interaction with study medication(s).
16. Have a diet incompatible with the clinic diet, in the opinion of the PI, within the 28 days prior to the first dose of study medication(s), and throughout the study.
17. Blood donation or significant blood loss within 90 days prior to dosing.
18. Plasma donation within 7 days prior to dosing.
19. Participation in another clinical trial within 90 days prior to dosing. The 90-day window will be derived from the date of the last study procedure (such as last blood collection or dosing) in the previous study to Day 1 of the current study.
20. Subjects who previously received ABP-700.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	03-08-2015
Aantal proefpersonen:	80
Type:	Onbekend

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ID

NL5099

NTR5231

: ANVN-01-04

Resultaten

Samenvatting resultaten

none.