A phase I, randomized, placebo-controlled, double blind, first time in human, escalating single-dose study to evaluate the safety, tolerability pharmacokinetics and pharmacodynamics of Neu-P12 in healthy male volunteers

Published: 09-01-2017
Last updated: 12-04-2024

Primary objectiveTo assess safety and tolerability of Neu-P12 in four different single doses of the drug. Secondary objectiveTo compare the pharmacokinetics, pharmacodynamics, safety, and tolerability of different single doses of Neu-P12.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45352

Source
ToetsingOnline

Brief title
Neu-P12 (CS0270)

Condition

- Other condition
- Peripheral neuropathies

Synonym

distressing and stinging pain, Neuropathic pain, nociceptive pain, numbness, pain - burning

Health condition

pain and itching

Research involving
Human

Sponsors and support

Primary sponsor: QPS Netherlands B.V.
Source(s) of monetary or material Support: Neurim Pharmaceuticals

Intervention

Keyword: pharmacodynamic, pharmacokinetic, safety, tolerability

Outcome measures

Primary outcome

To asses safety and tolerability of four different single doses of Neu-P12.

Secondary outcome

To compare the pharmacokinetics, pharmacodynamics, safety, and tolerability of

different single doses of Neu-P12.

Study description

Background summary

TrpV1, also known as the capsaicin receptor, is a known target for the management of chronic and neuropathic pain. TrpV1 is also activated by heat, a link between thermal pain and itch has been established for centuries. First, patients with chronic itch conditions have long reported that scalding heat helps to alleviate their pruritus. Second, topical application of the TrpV1 agonist, capsaicin, has been used to treat itch associated with many skin conditions. Therefore Nav1.7 antagonists and dual Nav1.7 and TrpV1 antagonists may be useful for the treatment of chronic pain and itch / pruritus

Neu-P12 is a novel investigational drug that is developed for the treatment of pain and/ or pruritus/itch. Its mechanism of action involves inhibition of

human Nav1.7/1.3 sodium channels and TrpV1 non-selective cation channels that are widely expressed in skin tissues, and peripheral sensory nerve fibers. Neu-P12 does not interact with COX 1 or 2 or opioid receptors and does not exhibit measurable affinity for the histamine, GABA, benzodiazepine, dopamine, adrenaline, acetylcholine, neuropeptide or opiate receptors suggesting a selective mode of action.

Study objective

Primary objective
To assess safety and tolerability of Neu-P12 in four different single doses of the drug.

Secondary objective
To compare the pharmacokinetics, pharmacodynamics, safety, and tolerability of different single doses of Neu-P12.

Study design

This study is a randomized, placebo-controlled, double blind, escalating single-dose study. The wash-out between subsequent cohorts will be at least 1 week.

Intervention

Neu-P12
Sunburn model
Venapunctions

Study burden and risks

ICF / risk analysis

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects have signed the informed consent form prior to any study related activity.
2. Subjects are healthy male volunteers between 18 and 55 years of age at the screening (inclusive).
3. Subject has a BMI * 18.0 kg/m and * 30.0 kg/m2 at the screening.
4. Subject can stay in the study center for 3 nights.
5. Subject is appropriate for the study in the judgement of the investigator, based on physical examination, laboratory tests, and subject*s interview.
6. Subject has a high probability for compliance with and completion of the study.
7. Male subjects must agree to either abstain from sexual intercourse or use a condom with spermicide during the duration of the study until 90 days after their last dose in the study.
8. Subjects are non-smoker for at least 6 months.
9. Subject must have skin type 1 or 2 according to Fitzpatrick Skin Typing Test. (not applicable for cohort 1).

Exclusion criteria

1. Subject shows clinically significant abnormalities in physical examination or vital signs, according to the investigator*s judgement.
2. Has a history of clinically significant endocrine, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, genitourinary or major neurological (including stroke and chronic seizures) abnormalities or diseases.
3. Has a history of significant and/or severe allergies.
4. Had major surgery, donated or lost 1 unit of blood or plasma (approximately 500 mL)

within 4 weeks prior to the pretrial (screening) visit.
5. Has participated in another investigational trial within 90 days prior to the first intake of the IMP of this study.
6. Subject has an abnormal laboratory result judged by the investigator as being clinically significant.
7. Subject has used any prescription drug or herbal medicine within 14 days, OTC or vitamin supplements within 7 days prior to Day 1.
8. Subject has tattoos on the skin areas to be exposed with UV radiation (not for cohort 1).
9. Standard liver function tests including ALT, AST, alkaline phosphatase, gamma-glutamyl transferase, lactate dehydrogenase and bilirubin (total and direct) do not exceed the upper limit of normal for the local laboratory during screening and day -1.
10. Subject has a positive urinary drug screen (incl. amphetamine, barbiturates, benzodiazepines, cocaine, marijuana, methadone, methamphetamine, morphine, phencyclidine, and tricyclic antidepressants).
11. History of abuse of alcohol or drugs in the last 2 years (alcohol >23 units/week).
12. Subject has a positive test for HIV antibody, HBsAg, or HCV antibody.
13. Subject has a QTc (Bazet) prolongation greater than or equal to 450 ms.
14. Subject has ECG with one or more of the following criteria (a single repeat is allowed for eligibility determination, at screening and day -1):
Pulse rate <45 and >100 bpm
PR Interval <110 and >200 msec
QRS duration <70 and >120 msec
15. Subject is unwilling or unable to adhere to any specific protocol restriction as mentioned in Section 8.3.3 of this protocol.
16. Male subject who plans to father a child during the course of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	08-02-2017
Enrollment:	32
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	placebo
Generic name:	placebo

Ethics review

Approved WMO Date:	09-01-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-01-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-02-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-02-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-005167-14-NL
CCMO	NL60373.056.17