A Phase 1, Single-Center, Single-Blind, Placebo and Propofol Controlled Study in Healthy Subjects to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Ascending Intravenous (IV) Infusion Doses of ABP-700

Published: 21-07-2014
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Primary objectives:- to assess the safety and tolerability of a single ascending intravenous (IV) infusion doses of the research medication.- to determine the maximum tolerated dose (MTD) of IV infusion doses of the research medication.Secundary...

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

Summary

ID

NL-OMON41980

Source
ToetsingOnline

Brief title
ANVN-02 (CS0224)

Condition

- Other condition

Synonym
Not applicable

Health condition

anesthesia

Research involving

Human

Sponsors and support

Primary sponsor: Annovation Biopharma, Inc. (a wholly owned subsidiary of The Medicines Company, Inc.)
Source(s) of monetary or material Support: Annovation Biopharma

Intervention

Keyword: PD, PK, Safety, Single blind

Outcome measures

Primary outcome

Safety, PK and PD.

Secondary outcome

Not applicable.

Study description

Background summary

The research medication is an IV anesthetic drug being developed for monitored anesthesia care (MAC) and/or general
anesthesia in patients undergoing diagnostic or therapeutic procedures.

Study objective

Primary objectives:
- to assess the safety and tolerability of a single ascending intravenous (IV) infusion doses of the research medication.
- to determine the maximum tolerated dose (MTD) of IV infusion doses of the research medication.

Secundary objectives:

- to characterize the pk of the research medication and it's primary metabolite
- to assess the pd of the research medication
- to investigate the dose-resonse and pk/pd relationships.

Study design

This study will be a single-blind, randomized, placebo and active controlled, single ascending dose study. There are 7 cohorts, consisting of 8 subjects within each cohort. Out of 8 subjects, 5 will receive research medication, 2 will receive propofol and 1 will receive a placebo. Pre-medication (medication prior to dosing of the study drug) will be administered in at least 2 cohorts. In at least one cohort there will be a bolus administered before the infusion dose.

In the 8th and 9th (potential expansion cohort of 8) cohort, 4 subjects will receive research medication without pre-medication followed by 4 subjects with premedication.

Intervention

The study will start with a screening. At the screening a physical examination will take place and a few other standard
medical assessments will be performed (ECG, vital signs). Furthermore a blood and urine sample will be taken for
laboratory tests and an alcohol breath test and drug screen will be done.

During the stay in the clinic the subject will receive the research medication once on Day 1. Safety will be monitored and
sedation/anesthesia will be assessed throughout thestudy. Arterial and venous serial blood samples will be collected. The
subjects will be asked for possible side effects onregular basis.

Finally, a follow-up visit will take place.

Study burden and risks

The dose levels for this study have been selected on the basis of research results in animals and healthy volunteers.

The study drug has previously been tested in 50 humans and was generally well tolerated. A number of side-effects, possibly linked to use of the test medication, were reported. musclesThe most common adverse events (occurring in >5% of ABP-700 treated subjects) include muscle twitching, apnea, hyperventilation, tachycardia, restlessness, increased blood pressure, hiccups, abnormal respiration, decreased oxygen saturation and emergence delirium which are all consistent with the mechanism of action observed with this type of

medication.

If you are assigned to a group receiving pre-treatment with fentanyl the most commonly experienced side effects include: respiratory depression (too shallow or slow breathing, shortness of breath, short periods of not breathing), skeletal and chest muscle rigidity and
slow heart rate.

All drugs have a potential risk of causing an allergic reaction, which if not treated promptly, could become life threatening. The subjects will be monitored for any allergic reactions and emergency treatment will be provided as needed.

The blood collection procedure is not dangerous, but may cause discomfort or bruising.
Occasionally, fainting or an infection at the bloodsampling site can occur.

Shaving may be required for proper placement of ECG patches. This may cause irritation or bleeding of the skin.

ECG patches may cause redness, itching, rash or blisters on the skin and/or hair loss due to removal of ECG patches.

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

Healthy adult men and/or women between 18 and 45 years of age (inclusive)

Exclusion criteria

Clinical significant abnormalities at medical research

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2014
Enrollment:	72
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	ABP-700
Generic name:	ABP-700
Product type:	Medicine
Brand name:	Diprivan
Generic name:	Propofol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sublimaze
Generic name:	Fentanyl
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-10-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-12-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-12-2014
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-06-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-06-2015
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	EUCTR2014-002332-13-NL
CCMO	NL49894.056.14