A SINGLE ORAL DOSE STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETIC PROFILE OF RADIPRODIL IN ADULT HEALTHY VOLUNTEERS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON42541

Source
ToetsingOnline

Brief title
Radiprodil SAD study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Infantile spasm, West syndrome

Research involving
Human

Sponsors and support

Primary sponsor: PRA Health Sciences
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Infantile spasms, Radiprodil

Outcome measures

Primary outcome

The purpose of the study is to investigate how quickly and to what extent

radiprodil is absorbed and eliminated from the body (this is called

pharmacokinetics).

Secondary outcome

Also 2 new blood sampling methods, allowing easier blood sampling in young

children, will be tested

Study description

Background summary

Radiprodil is a new investigational compound that may eventually be used for the treatment of convulsions in children under 3 years of age (Infantile spasm, West syndrome). Radiprodil binds to a protein in the neural cells (the N-methyl-D-aspartate receptor subtype 2B [NR2B]) and changes the sensitivity of the protein to a signaling agent (glutamate). As a result a decrease in uncoordinated muscle contractions (convulsions) is expected. Radiprodil is in development and is not registered as a drug but has been given to humans before.

Study objective

The purpose of the study is to investigate how quickly and to what extent radiprodil is absorbed and eliminated from the body (this is called pharmacokinetics). It will also be investigated to what extent radiprodil is tolerated. In addition, 2 new blood sampling methods, allowing easier blood

sampling in young children, will be tested.This study is not intended to improve your health, but is necessary for the further development of radiprodil.

Study design

The study will be performed in 1 part. The purpose of the study is to investigate how quickly and to what extent radiprodil is absorbed and eliminated from the body (this is called pharmacokinetics). It will also be investigated to what extent radiprodil is tolerated. In addition, 2 new blood sampling methods, allowing easier blood sampling in young children, will be tested.

Intervention

The study will consist of 1 period during which you will receive 30 mg radiprodil once. Radiprodil will be given as an oral suspension of 12 mL

Should, in the opinion of the investigators, unacceptable adverse effects appear, the study will be discontinued.

Study burden and risks

The possible adverse effects of the investigational procedures (e.g. the use of the indwelling cannula) are described in Chapter 8 of the information booklet.

All potential drugs cause adverse effects; the extent to which this occurs differs. radiprodil has been given to 118 healthy volunteers and 332 patients with neuropathic (nerve) pain The most frequently observed adverse effects in healthy volunteers were: headache, somnolence (feeling sleepy), dizziness, disturbance in attention, insomnia, altered mood, oropharyngeal (throat) pain, and euphoric mood, feeling abnormal, feeling drunk, vision blurred, amnesia, feeling hot, lethargy, palpitations and tremor. Adverse effects more frequently observed in patients, but not in healthy volunteers were fatigue, nausea, increased libido, constipation, decreased appetite, flatulence and increased heart rate. A few rare but serious adverse events that were assessed as at least possibly related to radiprodil included balance disorder, mental status changes, feeling confused and suicidal ideation. One patient with predisposing risk factors had a transient ischemic attack (mini-stroke). These events were observed only in patients with neuropathic pain exposed to radiprodil continuously after more than a week of treatment and were reversible. No serious adverse events occurred during the prior studies in healthy volunteers.

You should be aware that the aforementioned adverse effects and possibly other, still unknown adverse effects, may occur during the study. With the single dose

used in this study no serious adverse effects are expected.

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 male and female subjects
18-45 years, inclusive
BMI:18 to 30kg/m² (inclusive)

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study

within 60 days before the start of this study or being a blood donor within 60 days from the start of the study or in case of donating more than 1.5 liter of blood in the 10 months prior the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Radiprodil
Generic name:	Radiprodil

Ethics review

Approved WMO Date:	25-11-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-12-2015
Application type:	First submission

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	EUCTR2015-004376-29-NL
CCMO	NL55708.056.15