Single-center, open-label, non-randomized study investigating the excretion balance, pharmacokinetics and metabolism of a single oral dose of [14C]-labeled RO5285119 in healthy male subjects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON41196

Source
ToetsingOnline

Brief title
RO5285119 mass balance study

Condition

- Neurological disorders NEC

Synonym
ASD, Asperger's syndrome, Autism Disorder

Research involving

Human

Sponsors and support

Primary sponsor: F. Hoffmann-La Roche Ltd
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: 14C, ASD, RO5285119

Outcome measures

Primary outcome

To characterize the routes and rates of elimination of [14C]-labeled RO5285119

To assess the pharmacokinetics of total drug related material, RO5285119 and

its metabolite(s) as appropriate

Secondary outcome

To identify and quantify the metabolic profiles of RO5285119 in plasma, feces

and urine, based on radioactive metabolic profiling, and characterize any major

metabolite(s)

To explore the safety and tolerability of a single dose of RO5285119 in healthy

volunteers

Study description

Background summary

RO5285119 is a new investigational compound that may eventually be used for the treatment of Autism Spectrum Disorders (ASD), a group of neurodevelopmental disorders including Autism Disorder, Asperger*s syndrome, and pervasive developmental disorder * not otherwise specified (PDD-NOS). These disorders are typically characterized by social deficits, communication difficulties, stereotyped or repetitive behaviors and interests, and in some cases, cognitive delays. Evidence implicates that vasopressin may play a role in autism.

Vasopressin is a hormone that is involved in the regulation of blood pressure and the retention of water in the kidneys in the periphery and in the regulation of stress, anxiety and social behavior in the central nervous system. RO5285119 blocks activation of the vasopressin receptor and is in development for treatment of the core deficits in ASD.
RO5285119 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 the study medication is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). The compound to be administered will be labeled with 14-Carbon (14C) and is thus radioactive (also called radiolabeled). This enables the investigator to trace the compound in blood, plasma, urine and feces.

This study will be performed in 6 healthy male volunteers.

Study design

The actual study will consist of 1 period during which you will stay in the clinical research center in Zuidlaren for a minimum of 8 days (7 nights) and a maximum of 12 days (11 nights), followed by minimal 1 and maximal 4 additional short visits to the clinical research center in Zuidlaren.

Intervention

During the study the volunteer will receive the study medication after an overnight fast (at least 8 hours) as an oral solution of 10 milliliters. After administration of the study medication, the volunteer is required to drink an additional amount of 220 milliliters water. After this the vial that contained the study medication will be rinsed twice with 10 milliliters of water, which the volunteer will also be required to drink. Fasting will continue until 4 hours after administration of the study medication. During fasting and after intake of the study medication, the volunteer is allowed to drink water ad libitum with the exception of 1 hour prior to until 2 hours after administration of study medication.

Study burden and risks

To date, 3 studies testing the study medication have been carried out in healthy volunteers. A total of 129 healthy subjects participated in these studies: 43 healthy volunteers received single oral doses and 83 healthy volunteers received multiple doses of the study medication. Single doses up to the highest dose tested of 76 mg and multiple doses up to the highest tested dose of 52 mg once daily for 14 days were well tolerated. Overall, the most

common adverse events were headache, myalgia (muscle pain), diarrhoea, somnolence, abdominal pain, dizziness (postural) and back pain. One subject reported headache, aggression, and anxiety after a single dose of 32 mg. One subject was withdrawn from treatment due to muscle pain after receiving multiple doses of the study medication.

Procedurs: pain, minor bleeding, bruising, possible infection

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 subjects
35-64 yrs, inclusive

BMI: 18.0 - 30.0 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters 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):	02-06-2014
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-05-2014
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	EUCTR2014-000277-40-NL
CCMO	NL49267.056.14