A non-therapeutic feasibility study to evaluate the kinetics and test-retest repeatability and reproducibility of the radioligand [11C]-UCB-J for imaging synaptic density in healthy subjects and mild-to-moderate Alzheimer*s Disease subjects

Published: 06-06-2018
Last updated: 10-01-2025

Primary objective:* Assess the test-retest repeatability and reproducibility of radioligand [11C]-UCB-J binding.Secondary objective:* Compare the precision and accuracy of PET data analysis using 60 versus 90 minutes of scan data.* Assess group…

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48549

Source
ToetsingOnline

Brief title
170439 - RDN-NI-001

Condition

- Other condition

Synonym
Alzheimer, dementia

Health condition

Alzheimer's Disease

Research involving

Human

Sponsors and support

Primary sponsor: Rodin Therapeutics, Inc.
Source(s) of monetary or material Support: Rodin Therapeutics Inc.

Intervention

Keyword: Alzheimer, Non-therapeutic, Radioligand [11C]-UCB-J, Reproducibility

Outcome measures

Primary outcome

[11C]-UCB-J Kinetics Parameters

PET Parameters

Safety and Tolerability Parameters

Secondary outcome

Biomarker Parameters

Study description

Background summary

This study is designed to quantify reproducibility of [11C]-UCB-J over a therapeutically relevant 28-day period and inform potential utilization of this tracer in future interventional studies.

Study objective

Primary objective:
* Assess the test-retest repeatability and reproducibility of radioligand [11C]-UCB-J binding.

Secondary objective:
* Compare the precision and accuracy of PET data analysis using 60 versus 90 minutes of scan data.
* Assess group differences in [11C]-UCB-J binding in pre-defined brain regions at each assessment time point.

Exploratory objective:
* Assess plasma-derived central nervous system (CNS) biomarkers.

Study design

After assessing eligibility during a 4-week screening period, approximately 20 subjects will participate in the PET acquisition phase of the study. Drop-outs or unevaluable subjects may be replaced for a target sample size of 20 completed and evaluable subjects.

PET scanning duration will be initially set to 90 minutes. After a minimum of 4 subjects have completed baseline and Day 28 scans, 90 minute and 60 minute scan data will be analyzed. Based on this analysis, and at the discretion of the investigator, it will be decided whether the remaining subjects will require 60 or 90 minute scans.

Intervention

Injection with [11C]-UCB-J .

Study burden and risks

This study is being conducted in healthy volunteers and mild-to-moderate Alzeheimer diseased volunteers. There are no anticipated benefitis or risks of the ligand [11C]-UCB-J. Please see the IMPD for futher information.

Contacts

Public
Rodin Therapeutics, Inc.

Technology Square 300
Cambridge MA 02139
US
Scientific
Rodin Therapeutics, Inc.

Technology Square 300

Cambridge MA 02139
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Group 1:
Healthy male or female age 50 * 80 years old, inclusive, at the time of informed consent.;Group 2:
Adult males or females age 50 * 80 years old, inclusive, at the time of informed consent.
Confirmed diagnosis of mild-to-moderate AD.

Exclusion criteria

History or current evidence of any clinically significant cardiovascular, endocrinologic, hematologic, hepatobiliary, immunologic, metabolic, urologic, pulmonary, neurologic (with the exception of AD in Group 2), psychiatric, renal, or other major disease, as determined by the Investigator.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-08-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N. Ap.
Generic name:	[11C]-UCB-J

Ethics review

Approved WMO Date:	06-06-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-06-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	24-01-2019
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	EUCTR2018-001503-37-NL
CCMO	NL65992.056.18
Other	see J

Study results

Date completed:	02-08-2019
Results posted:	12-03-2020

First publication
14-02-2020