ISRCTN16338271 https://doi.org/10.1186/ISRCTN16338271

Phase 1 Trial: RD 800.36129 (WVE-006-001)

Submission date
18/12/2023

Recruitment status
No longer recruiting

Registration date
18/12/2023

Overall study status
Deferred

Last Edited
18/12/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008635

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
WVE-006-001, IRAS 1008635

Study information

Scientific Title
Phase 1 Trial: RD 800.36129 (WVE-006-001)

Acronym
RestorAATion-1

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 19/10/2023, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941119; Wales.REC2@wales.nhs.uk), ref: 23/WA/0236

2. Approved 06/11/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 51170/0010/001-0001

Study design
Two-part first-in-human trial in up to 56 healthy participants

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility, Other

Study type(s)
Other, Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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Secondary outcome measures
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Overall study start date
11/08/2023

Completion date
31/12/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
56

Key exclusion criteria
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Date of first enrolment
14/11/2023

Date of final enrolment
03/06/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec Research Limited
Simbec House Merthyr Tydfil Industrial Park
Merthyr Tydfil Industrial Park
Pentrebach
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Mid Glamorgan

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Sponsor information

Organisation
Wave Life Sciences (United States)

Sponsor details
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Sponsor type
Industry

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ROR
https://ror.org/015x34y38

Funder(s)

Funder type
Industry

Funder Name
Wave Life Sciences UK Limited

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
30/06/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available