ISRCTN12117857 https://doi.org/10.1186/ISRCTN12117857

Phase I trial: Parexel code: PXL 269850

Submission date 29/06/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/06/2023	**Overall study status** Deferred	
Last Edited 30/04/2025	**Condition category** Other	

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)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2022-003322-50

Integrated Research Application System (IRAS)
1006840

Protocol serial number
PXL 269850, NMD1343-01-0001

Study information

Scientific Title
Phase I trial: Parexel code: PXL 269850 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 09/02/2023, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8154; harrow.rec@hra.nhs.uk), ref: 23/LO/0007

2. Approved 21/02/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 57479/0001/001-0001

Primary study design
Interventional

Study design
Phase I first-in-human study to assess safety, tolerability and pharmacokinetics in healthy volunteers

Study type(s)
Safety

Health condition(s) or problem(s) studied
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Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
The sponsor has confirmed that the trial meets the criteria for 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.

Primary outcome(s)
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.

Key secondary outcome(s)
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.

Completion date
31/05/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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Date of first enrolment
21/03/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Parexel Early Phase Clinical Unit
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
NMD Pharma

Funder(s)

Funder type
Industry

Funder Name
NMD Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the study being conducted in healthy volunteers

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No