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 [X] 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

EudraCT/CTIS number
2022-003322-50

IRAS number
1006840

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006840, 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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety

Participant information sheet
Not available in web format

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

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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

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 measure
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.

Secondary outcome measures
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.

Overall study start date
20/12/2022

Completion date
31/05/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
88

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
England

United Kingdom

Study participating centre
Parexel Early Phase Clinical Unit
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
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Sponsor information

Organisation
NMD Pharma

Sponsor details
Palle Juul-Jensens Boulevard 82
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
NMD Pharma

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
30/11/2026

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