

Pilot phase I, safety and pharmacokinetic study in healthy participants

Submission date 18/11/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/11/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/11/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1012318

Study information

Scientific Title

Pilot phase I, safety and pharmacokinetic study in healthy participants

Acronym

KZ-01

Study objectives

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Ethics approval required

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Ethics approval(s)

approved 22/09/2025, North West - Greater Manchester Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; N/A; gmcentral.rec@hra.nhs.uk), ref: 25/NW/0216

Study design

Pilot Phase I, safety and pharmacokinetic study in healthy participants

Primary study design

Interventional

Study type(s)

Safety

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

31/12/2025

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

Yes

Age group

Mixed

Sex

All

Total final enrolment

12

Key exclusion criteria

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Date of first enrolment

01/10/2025

Date of final enrolment

05/11/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Medicines Evaluation Unit Limited**

The Langley Building

Southmoor Road

Wythenshawe

Manchester

England

M23 9QZ

Sponsor information

Organisation

Mexichem UK Ltd

Funder(s)

Funder type

Not defined

Funder Name

Mexichem UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date