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Pilot phase I, safety and pharmacokinetic study in healthy participants

Submission date 18/11/2025	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 18/11/2025	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 18/11/2025	**Condition category** Other	[ ] 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.

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Public, Scientific

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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
Ethics approval required

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

Primary study design
Interventional

Study design
Pilot Phase I, safety and pharmacokinetic study in healthy participants

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)
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
31/12/2025

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