ISRCTN16585188 https://doi.org/10.1186/ISRCTN16585188

Phase I Trial: 323476

Submission date 10/09/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/09/2024	**Overall study status** Deferred	
Last Edited 13/09/2024	**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

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Scientific, Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323476

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 323476, CPMS 59146

Study information

Scientific Title
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)
approved 22/03/2024, London - Dulwich Research Ethics Committee (2nd Floor, 2 Redman Place, London, E20 1JO, United Kingdom; 0207 104 8290; dulwich.rec@hra.nhs.uk), ref: 24/LO/0134

Study design
Multi-site trial with 50 participants

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Phase
Not Applicable

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
01/06/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
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Date of first enrolment
20/09/2024

Date of final enrolment
01/04/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's Hospital Laboratory
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
SAVA Technologies Ltd.

Funder(s)

Funder type
Industry

Funder Name
SAVA Technologies Ltd.

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes