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

# Phase I Trial: 323476

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| **Submission date**<br>10/09/2024 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>13/09/2024 | **Overall study status**<br>Deferred | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>13/09/2024 | **Condition category**<br>Other | [_] Individual participant data<br>[X] 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

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Scientific, Principal Investigator

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Public

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# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**
323476

**ClinicalTrials.gov number**
Nil known

**Secondary identifying numbers**
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**
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.

**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

**Secondary study design**
Non randomised study

**Study setting(s)**
Other

**Study type(s)**
Other

**Participant information sheet**
Not available in web format.

### 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

### Pharmaceutical study type(s)
Not Applicable

### Phase
Not Applicable

### Drug/device/biological/vaccine name(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.

### 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
01/06/2023

### Completion date
01/06/2025

## Eligibility

### Key inclusion criteria
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### Participant type(s)
Other

### Age group
Not Specified

### Sex
Both

### Target number of participants
50

### Key exclusion criteria
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.

### Date of first enrolment
20/09/2024

### Date of final enrolment
01/04/2025

## Locations

### Countries of recruitment
England

United Kingdom

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

## Sponsor information

### Organisation
SAVA Technologies Ltd.

### Sponsor details
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London
England
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### Sponsor type
Industry

# Funder(s)

### Funder type
Industry

### Funder Name
SAVA Technologies Ltd.

# 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 may be posted on or after the date of publication of full trial details.

### Intention to publish date
03/08/2027

### 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