ISRCTN17328380 https://doi.org/10.1186/ISRCTN17328380

# Phase 1 trial HMR code: 23-011

| | | |
|---|---|---|
| **Submission date**<br>26/03/2024 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>02/04/2024 | **Overall study status**<br>Deferred | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>29/04/2025 | **Condition category**<br>Other | [_] Individual participant data |

**Plain English Summary**
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.

## Contact information

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
1009554

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
IRAS 1009554, HMR code: 23-011, Sponsor code: ASN51-105

# Study information

### Scientific Title
Phase 1 trial HMR code: 23-011
The full scientific title will be published within 30 months after the end of the trial

### Study hypothesis
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.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
1. Approved 04/04/2024, South Central – Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8171; oxforda.rec@hra.nhs.uk), ref: 24/SC/0041

2. Approved 05/04/2024, Medicines and Healthcare products Regulatory Agency (MHRA) (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 50212/0004/001-0001

### Study design
Drug-drug interaction trial in up to 16 healthy volunteers

### Primary study design
Interventional

### Secondary study design
Open-label

### Study setting(s)
Other

### Study type(s)
Other

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

### Condition
Healthy volunteers

### Interventions
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.

### Intervention Type
Drug

### Pharmaceutical study type(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.

### 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 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.

### Secondary outcome measures
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.

### Overall study start date
16/02/2024

### Overall study end date
22/09/2024

## Eligibility

### Participant inclusion criteria
Healthy human volunteer

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Sex
Both

### Target number of participants
Up to 16

### Participant exclusion criteria
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.

### Recruitment start date
23/04/2024

### Recruitment end date
22/06/2024

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Hammersmith Medicines Research (HMR)**
Cumberland Avenue, Park Royal
London
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NW10 7EW

## Sponsor information

### Organisation
Asceneuron (Switzerland)

### Sponsor details
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### Sponsor type
Industry

### Website
https://www.asceneuron.com/

### ROR
https://ror.org/02sbchm13

## Funder(s)

### Funder type
Industry

### Funder Name
Asceneuron S.A.

## 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 1 study and the negligible benefit to the public of phase 1 information. Results will be posted on or after the date of publication of full trial details.

### Intention to publish date
22/03/2027

### 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | | 29/04/2025 | No | No |