ISRCTN67246142 https://doi.org/10.1186/ISRCTN67246142

Phase 1 Trial: CA38132

Submission date 13/04/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 15/04/2024	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 15/04/2024	**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.

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1006689

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006689, CA38132

Study information

Scientific Title
Phase 1 Trial: CA38132
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)
1. Approved 21/03/2023, London - London Bridge Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048387; londonbridge.rec@hra.nhs.uk), ref: 22/LO/0842

2. Approved 22/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 2030806000; info@mhra.gov.uk), ref: CTA 52490/0004/001-0001

Study design
Phase 1 Safety Study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Safety

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions

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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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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
21/10/2022

Completion date
10/08/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
60

Total final enrolment
51

Key exclusion criteria
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Date of first enrolment
13/04/2023

Date of final enrolment
03/07/2023

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Celerion GB Limited
22-24 Lisburn Road
Belfast
United Kingdom
BT9 6AD

Sponsor information

Organisation
Pliant (United States)

Sponsor details
331 Oyster Point Boulevard
South San Francisco

United States of America
CA 94080
+1 650-481-6770
gcosgrove@pliantrx.com

Sponsor type
Industry

Website
https://pliantrx.com/

ROR
https://ror.org/02myr1w18

Funder(s)

Funder type
Industry

Funder Name
Pliant Therapeutics Inc.

Results and Publications

Publication and dissemination plan
Full trial details may 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
10/02/2026

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