ISRCTN13284995 https://doi.org/10.1186/ISRCTN13284995

Phase I trial, IQVIA Biotech code: Breye-C22-1005

Submission date	Recruitment status	[ ] Prospectively registered
05/05/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/11/2023	Deferred	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/10/2024	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol
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

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1007664

Protocol serial number
Breye-C22-1005, IRAS 1007664, CPMS 55664

Study information

Scientific Title
Phase I trial, IQVIA Biotech code: Breye-C22-1005 [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
Old ethics approval format

Ethics approval(s)
Approval pending, ref: 23/NW/0152

Study design
Phase I trial in 24 patients

Primary study design
Interventional

Study type(s)
Treatment

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)

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Key secondary outcome(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

Completion date
30/04/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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Date of first enrolment
31/10/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

Germany

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Breye Therapeutics ApS

Funder(s)

Funder type
Industry

Funder Name
Breye Therapeutics ApS

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