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	Eve 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

Contact name

Dr Phillip Burgess

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007664

ClinicalTrials.gov (NCT)

Nil known

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

Study outputs

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

Participant information sheet