

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

Submission date 05/05/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/11/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/10/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Integrated Research Application System (IRAS)

1007664

Central Portfolio Management System (CPMS)

55664

Protocol serial number

Breye-C22-1005

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)

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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