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

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

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

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

EudraCT/CTIS number
Nil known

IRAS number
1007664

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Dose response

Phase
Phase I

Drug/device/biological/vaccine name(s)
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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
02/05/2023

Completion date
30/04/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24

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
Germany

United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Breye Therapeutics ApS

Sponsor details
Agern Allé 24
Hørsholm
Denmark
2970
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info@breye.com

Sponsor type
Industry

Website
https://breye.com

Funder(s)

Funder type
Industry

Funder Name
Breye Therapeutics ApS

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 highly 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
31/10/2026

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