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Pharmacokinetic study to the open-label Phase of NUC-5/primary sclerosing cholangitis study

Submission date 31/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/02/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 17/02/2025	**Condition category** Other	[_] Individual participant data [X] 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.

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Additional identifiers

EudraCT/CTIS number
2022-000261-40, 2023-507027-37

IRAS number
1008879

ClinicalTrials.gov number

Secondary identifying numbers
58477

Study information

Scientific Title
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Acronym
NUC-11/BIO

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 18/12/2023, West Midlands – Edgbaston Research Ethics Committee (2 Redman Place, Stratford, E20 1 JQ, United Kingdom; +44 (0)207 104 8000; edgbaston.rec@hra.nhs.uk), ref: 23 /WM/0230

Study design
Interventional pharmacokinetic study

Primary study design
Interventional

Secondary study design
Pharmacokinetic study

Study setting(s)
Hospital

Study type(s)
Safety

Participant information sheet

Health condition(s) or problem(s) studied
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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
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Overall study start date
01/07/2023

Completion date
31/12/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
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Date of first enrolment
16/09/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospital Birmingham NHS Foundation Trust
Robert Aitken Institute of Clinical Research
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
Royal Free Hospital
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Sponsor type
Industry

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ROR
https://ror.org/05sh9vm75

Funder(s)

Funder type
Industry

Funder Name
Dr. Falk Pharma

Alternative Name(s)
Falk Pharma, Dr Falk Pharma, Dr Falk Pharma GmbH, Dr. Falk Pharma GmbH, Dr. Falk Pharma UK Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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 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
31/01/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date