ISRCTN65190051 https://doi.org/10.1186/ISRCTN65190051

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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 17/02/2025	**Overall study status** Deferred	
Last Edited 17/02/2025	**Condition category** Other	

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

Clinical Trials Information System (CTIS)
2022-000261-40

Clinical Trials Information System (CTIS)
2023-507027-37

Integrated Research Application System (IRAS)
1008879

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional pharmacokinetic study

Study type(s)
Safety

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
31/12/2024

Eligibility

Key inclusion criteria

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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Study participating centre

Royal Free Hospital
Liver Transplantation
Pond Street
London
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NW3 2QG

Sponsor information

Organisation
Dr Falk Pharma (Germany)

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

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