

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

Submission date 31/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/02/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/02/2025	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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.

Contact information

Type(s)

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Additional identifiers

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

Study design

Interventional pharmacokinetic study

Primary study design

Interventional

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

United Kingdom

B15 2TH

Study participating centre**Royal Free Hospital**

Liver Transplantation

Pond Street

London
United Kingdom
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