Single dose study to evaluate how intravenous administered difelikefalin is absorbed by and cleared from Adolescents on Haemodialysis

05/04/2025 03:46:03

Main Information

Primary registry identifying number

LBCTR2022125201

Protocol number

KOR-PED-201

MOH registration number

Study registered at the country of origin

No

Study registered at the country of origin: Specify

Prevalence of the disease is low in Switzerland and potential sites might not be able to enroll patients during the planned duration of the study

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

Primary sponsor

Vifor Fresenius Medical Care Renal Pharma Ltd.

Primary sponsor: Country of origin

Switzerland

Date of registration in primary registry

07/02/2023

Date of registration in national regulatory agency

Public title

Single dose study to evaluate how intravenous administered difelikefalin is absorbed by and cleared from Adolescents on Haemodialysis

Acronym

Scientific title

An Open-label, Single Arm Study to Evaluate the Pharmacokinetics of a Single Dose of Intravenous Difelikefalin in Adolescents Aged 12 to 17 Years on Haemodialysis

Acronym

Brief summary of the study: English

This is an open-label study to evaluate the activity of a single dose of intravenous Difelikefalin in the body, including its absorption, distribution and excretion from the body, in adolescents aged 12 to 17 Years on haemodialysis.

Brief summary of the study: Arabic

هذه دراسة مفتوحة التسمية لتقييم نشاط جرعة واحدة من Difelikefalin عن طريق الوريد في الجسم ، بما في ذلك امتصاصه، توزيعه وإفرازه من الجسم ، لدى المراهقين الذين تتراوح أعمارهم بين 12 و17 عامًا يخضعون لغسيل الكلى .

Health conditions/problem studied: Specify

Patients with chronic kidney disease undergoing hemodialysis

Interventions: Specify

Drug: Difelikefalin (CR845)

Key inclusion and exclusion criteria: Inclusion criteria

1. End-stage renal disease (ESRD) subjects who have been on HD for at least 3 months and are currently on HD at least 3 times per week.

Subjects with or without associated pruritus may enroll.
2. Males or females 12 to 17 years of age, at the time of consent.
3. Has a prescription dry body weight ≥20 kg and ≤100 kg.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

12

Key inclusion and exclusion criteria: Age maximum

17

Key inclusion and exclusion criteria: Exclusion criteria

1. Known to be non-compliant with HD treatments and deemed unlikely to complete the study by the Investigator (i.e., has a history of missed HD
sessions due to non-adherence in the past 2 months).
2. Planned or anticipated to receive a kidney transplant during the study. Note: Being on a kidney transplant list is not an exclusion criterion.
3. Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST) greater than 2.5 × the reference upper limit of normal (ULN), or bilirubin greater than 4 × the ULN at screening.
4. Subject has known hypersensitivity to the study drug or any components of the difelikefalin formulation.
5. Known history of allergic reaction to opiates such as hives. Note: Side effects related to the use of opioids such as constipation or nausea would not exclude the subjects from the study.
6. Previous participation in this study.
7. Known or suspected history of alcohol, narcotic, or other drug abuse or substance dependence within 12 months prior to screening.
8. Acute or unstable medical condition(s) which in the opinion of the Investigator would pose undue risk to the subject or would impede complete
collection of evaluable data.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Single Arm Study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

2

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Worldwide

IMP has market authorization: Specify

USA, Germany, Austria, Netherlands

Name of IMP

KORSUVA (US), KAPRUVIA (EU)

Year of authorization

2021

Month of authorization

8

Type of IMP

Others

Pharmaceutical class

Selective Kappa-Opioid Receptor (KOR) full agonist

Therapeutic indication

moderate-to-severe pruritus associated with chronic kidney disease in patients on haemodialysis

Therapeutic benefit

Opioid receptors are involved in the modulation of pruritus and pain signals and consist mainly of 3 subtypes, classified as mu, kappa, and delta. These receptor subtypes are found in the CNS (ie, brain and spinal cord), on sensory ganglionic neurons and their nerve fibers innervating peripheral tissues such as skin, and on certain cell types of the immune system. Most clinically used opioid analgesics act primarily via activation of mu-opioid receptors located in the CNS and peripheral nervous system. As such, there are associated with a wide array of side effects, such as sedation, respiratory depression, abuse liability, cardiovascular collapse, and death.
To avoid these undesirable effects, difelikefalin was designed to only activate KORs, which are known to modulate visceral and inflammatory pain, pruritus, and inflammatory signals in animals and humans.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

3

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

02/01/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

30/06/2023

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

-

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
EU Clinical Trials Register	EudraCT Number: 2021-000894-94

Sources of Monetary or Material Support

Name
Vifor Fresenius Medical Care Renal Pharma Ltd.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Diana Salameh	Beirut	Lebanon	+961 3 902 515	diana.salame@worldwide.com	Worldwide Clinical Trials
Scientific	Milica Enoiu	Flughofstrasse 61, CH-8152 Glattbrugg	Switzerland	-	milica.enoiu@viforpharma.com	Vifor Fresenius Medical Care Renal Pharma Ltd.

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu de France hospital	Dr. Chebl Mourani	Pediatric Nephrology	Approved
Saint Georges University Medical Center	Dr. Pauline Abou Jaoude	Pediatric Nephrology	Pending

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	02/11/2022	Pr. Sami Richa	-	+9611604000

Countries of Recruitment

Name
Lebanon
Italy
United Kingdom

Health Conditions or Problems Studied

Condition	Code	Keyword
Chronic kidney disease associated pruritus in haemodialysis patients	Pruritus (L29)	pruritus, kidney disease, pediatric
Chronic kidney disease associated pruritus in hemodialysis patients	Chronic renal failure (N18)	CKD, associated pruritus

Interventions

Intervention	Description	Keyword
Drug	Difelikefalin (CR845)	KOR agonist

Primary Outcomes

Name	Time Points	Measure
PK profile of difelikefalin after a single dose post-HD	Day 1, 2 and 3	PK sampling

Key Secondary Outcomes

Name	Time Points	Measure
Incidence of adverse events (AEs) and serious adverse events (SAEs)	From Day 1 to Day 7	Documentation of all AEs occurred during conduct of study
Incidence of adverse events (AEs) and serious adverse events (SAEs)	From Day 1 to Day 7	Measurement of vital signs, ECG measurements, blood tests

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files