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Safety and efficacy of a new solution, XyloCore, for peritoneal dialysis

Submission date
26/04/2022

Recruitment status
No longer recruiting

Registration date
28/04/2022

Overall study status
Ongoing

Last Edited
06/11/2024

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Peritoneal dialysis is a treatment for kidney failure that uses the lining of the abdomen (peritoneum) to filter the blood inside the body. XyloCore is a new solution for peritoneal dialysis. Current commercial peritoneal dialysis solutions have a high glucose content that could alter the function of the peritoneum and increase glycemia (blood glucose level) when administered for a long time. Xylocore solutions substitute a part of this glucose with other agents (xylitol and carnitine) to preserve the function of the peritoneum and glycemia in the long term while achieving similar effectiveness compared to current commercial solutions. Preliminary results of a clinical study (phase 2) on XyloCore showed improved effectiveness and fluid removal without relevant undesirable effects. Based on the promising results from phase 2, the current study is designed to investigate if XyloCore has similar effectiveness to the commercial products containing glucose.

Who can participate?
Patients aged 18 years and over with end-stage kidney disease and treated with peritoneal dialysis in the last 3 months

What does the study involve?
There are two treatment groups - XyloCore and standard of care peritoneal solution. Patients who are eligible to participate in the study will attend an initial visit to the clinic to confirm their eligibility and a second visit when they will start treatment with XyloCore or the standard of care solution. The duration of the treatment is 6 months and during this period they will have three clinic visits - at days 30, 120 and 180. During these clinic visits they will have blood tests, physical examinations, and assessments of their vital signs and kidney function. After the treatment period patients will be switched back to the standard of care treatment.

What are the possible benefits and risks of participating?
It has been observed that patients with a peritoneal catheter may have a risk of infections, namely peritonitis (inflammation of the peritoneum). In patients performing PD the risk of peritonitis is one episode over 3 years. Anyway more than 95% of PD-related peritonitis

recovered by short-term treatment with antibiotics. The risk of peritonitis is also associated with insufficient training in PD bag correct use. The study team will train the patient to use the PD bag.

Where is the study run from?
Sintesi Research (Italy)

When is the study starting and how long is it expected to run for?
April 2022 to December 2025

Who is funding the study?
Iperboreal Pharma (Italy)

Who is the main contact?
Dr Mark Lambie
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

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2019-004183-21

IRAS number
1005365

ClinicalTrials.gov number
NCT03994471

Secondary identifying numbers
IP-001-18, IRAS 1005365, CPMS 44912

Study information

Scientific Title
A study to evaluate the efficacy and safety of XyloCore, a glucose-sparing experimental solution, for peritoneal dialysis

Study objectives
The primary objective of this study is to demonstrate the non-inferiority of XyloCore compared to the standard treatment of glucose PD solutions, with regards to the weekly Kt/Vurea.

The study will also measure:
1. Changes from the baseline values of LDL, HDL and total cholesterol, serum triglycerides, HbA1c (glycated haemoglobin), and insulin
2. Changes from the baseline values of hemoglobin and EPO requirements (medication used to manage anemia in patients on dialysis)
3. Patients' subjective assessment of fatigue (Chalder Fatigue Scale)
4. Peritoneal ultrafiltration
5. Diuresis (24 hours urinary volume)
6. Residual kidney function (measured as the arithmetic mean of urinary urea and creatinine clearance)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2022, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (Equinox House, City link, Nottingham, NG2 4LA, UK; Tel: not applicable; cambsandherts.rec@hra.nhs.uk), ref: 22/EE/0102

Study design
Open randomized controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions

The purpose of the study is to evaluate if XyloCore, a new solution for peritoneal dialysis, is as safe as the commercially available solutions. There are two treatment groups: XyloCore and standard of care peritoneal solution. Patients who are eligible to participate in the study will attend an initial visit to the clinic to confirm their eligibility and a second visit when they will start treatment with XyloCore or the standard of care solution. The duration of the treatment is 6 months and during this period they will have three clinic visits at days 30, 120 and 180. During these clinic visits they will have blood tests, physical exams, and assessment of their vital signs and kidney function. After the treatment period patients will be switched back to the standard of care treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Total weekly Kt/Vurea after a 24-week period using the assigned PD solution, assessed using a peritoneal function test. In brief, in order to measure solutes (urea) and calculate peritoneal and renal Kt/V (summing up to total Kt/V), blood, spent effluent (drained volume or dialysate outflow) and urine covering 24 hours will be collected.

Secondary outcome measures
1. LDL, HDL and total cholesterol, serum triglycerides, HbA1c (glycated haemoglobin), and insulin measured using lab assessment at 6 months
2. Hemoglobin and EPO requirements measured using lab assessment at 6 months
3. Patients' subjective assessment of fatigue using the Chalder Fatigue Scale at 6 months
4. Peritoneal ultrafiltration measured using lab assessment at 6 months
5. Diuresis (24 hours urinary volume) measured using lab assessment at 6 months
6. Residual kidney function, measured as the arithmetic mean of urinary urea and creatinine clearance at 6 months

Overall study start date
22/04/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Diagnosed with end-stage renal disease (ESRD) and treated with continuous ambulatory peritoneal dialysis (CAPD) in the last 3 months
3. In stable clinical condition during the 3 months before screening as demonstrated by the absence of non-elective hospitalization and major cardiovascular events
4. Have not experienced peritonitis episodes in the last 3 months
5. In treatment with prescribed Extraneal (nocturnal long-dwell exchange) for at least 1 month
6. In treatment with 2 or 3 diurnal short-dwell prescribed exchanges with Physioneal (including Clear-Flex bag), Fixioneal, Dianeal, Dianeal low calcium (1.36%, 2.27% or 3.86% glucose), Balance, Bivavera, Bicanova or Equibalance (1.5%, 2.3%, 4.25% glucose)
7. Weekly Kt/V urea measurement ≥1.7 (See Annex 1)
8. Followed/treated by the participating clinical Center/Investigator in the last 3 months

9. Understanding the nature of the study and providing their informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
1. History of drug or alcohol abuse in the 6 months prior to entering the protocol
2. In treatment with androgens
3. Clinically significant abnormal liver function test (Gamma-GT >4 times the upper normal limit)
4. Acute infectious conditions (i.e. pulmonary infection, acute hepatitis, high or low urinary tract infections, renal parenchymal infection, pericarditis, etc)
5. Expected patient's survival shorter than the trial duration
6. L-Carnitine therapy in the month prior to entering the protocol
7. Have used any investigational drug in the 3 months prior to entering the protocol
8. Female patients who are pregnant or breastfeeding
9. Female patients of childbearing age (less than 24 months after the last menstrual cycle) who do not use adequate contraception
10. Patients affected by primary hyperoxaluria as per known medical history
11. Patients with serum levels of uric acid >7.2 mg/dl (male and postmenopausal women) or >6.0 mg/dl (premenopausal women)
12. Patients with a major cardiovascular event in the last 3 months
13. Patients with advanced cardiac failure (NYHA 4)

Date of first enrolment
30/10/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Denmark

England

Germany

Israel

Italy

Spain

Sweden

United Kingdom

Study participating centre
University Hospitals of North Midlands
Newcastle Road
Stoke-on-Trent
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ST4 6QG

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
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Study participating centre
Hammersmith Hospital
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Study participating centre
Kent and Canterbury Hospital
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CT1 3NG

Study participating centre

St Lukes Hospital
Little Horton Lane
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BD5 0NA

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
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OX3 7LE

Study participating centre
Sheffield Kidney Institute
Northern General Hospital
Herries Rd
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United Kingdom
S5 7AU

Study participating centre
Cardiff and Vale University Health Board
Wales Kidney Research Unit, Heath Park Campus
Cardiff
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CF14 4XN

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton (UHDB), Uttoxeter Rd
Derby
United Kingdom
DE22 3NE

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham City Hospital, Renal Unit, Hucknall Rd
Nottingham

United Kingdom
NG5 1PB

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Royal Sussex County Hospital, Eastern Road, Brighton and Hove
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Sponsor information

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Sintesi Research

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Iperboreal Pharma

Results and Publications

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Conference presentation
3. Submission to regulatory authorities
4. The data will be published in scientific journals

Intention to publish date
01/09/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No