ISRCTN18337938 https://doi.org/10.1186/ISRCTN18337938

Detecting early infection in people treated with peritoneal dialysis by analysing the cloudiness of dialysis fluid

Submission date
30/07/2026

Recruitment status
Recruiting

Registration date
25/08/2026

Overall study status
Ongoing

Last Edited
25/08/2026

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol
Background and study aims
The aim of this study is to develop a simple and accessible diagnostic tool that could help detect cloudy dialysis fluid earlier and more objectively. This tool could potentially be used both at home by patients receiving peritoneal dialysis and in hospitals. The study will combine physical measurements, visual assessment, and laboratory analysis of dialysis fluid. Machine learning algorithms will be used to identify early markers of peritoneal dialysis-associated peritonitis. The study will also explore the potential role of bacteriophages in the diagnosis and treatment of peritonitis. In the future, such a tool could help patients recognise infection earlier, start treatment sooner, reduce hospitalisations, and improve treatment outcomes.

Who can participate?
Adult patients (18 years and older) receiving peritoneal dialysis at Pauls Stradiņš Clinical University Hospital in Riga, Latvia.

What does the study involve?
Dialysis fluid samples from patients will be analysed using laboratory tests, physical measurements, and image analysis. Photographs of dialysis fluid will be taken under standardised conditions. The collected data will be used to develop computer-based models that may help detect early signs of peritoneal dialysis-associated peritonitis.

What are the possible benefits and risks of participating?
Participants are not expected to receive direct medical benefit from taking part in the study. However, the results may help improve future diagnostic methods for detecting peritoneal dialysis-associated peritonitis earlier. The study mainly uses dialysis fluid that would normally be discarded, therefore no significant additional risks are expected.

Where is the study run from?
The study is conducted at the Nephrology Centre of Pauls Stradiņš Clinical University Hospital in Riga, Latvia, in collaboration with Riga Stradiņš University and the Institute of Electronics and Computer Science.

When is the study starting and how long is it expected to run for?
January 2026 to December 2028.

Who is funding the study?
The study is funded by the Latvian Council of Science (Fundamental and Applied Research Programme, FLPP).

Who is the main contact?
Anna Jana Saulīte, annajana.saulite@rsu.lv

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Dr Kārlis Rācenis

ORCID ID
https://orcid.org/0000-0001-7123-4048

Contact details
Dzirciema street 16
Riga
Latvia
LV-1007
+371 67061583
karlis.racenis@rsu.lv

Type(s)
Public

Contact name
None Anna Jana Saulīte

ORCID ID
https://orcid.org/0000-0003-3504-8541

Contact details
Dzirciema street 16
Riga
Latvia
LV-1007
+371 67061583
annajana.saulite@rsu.lv

Additional identifiers

Latvian Fundamental and Applied Research Programme (FLPP) project
lzp-2025/1-0413

Study information

Scientific Title
CLEAR-PD: Early detection of peritonitis in patients receiving peritoneal dialysis using digital image analysis of dialysis fluid cloudiness compared with the current diagnostic standard of dialysate leukocyte count

Acronym
CLEAR-PD

Study objectives
Peritoneal dialysis-associated peritonitis remains one of the most serious complications of peritoneal dialysis, and early diagnosis is essential to ensure timely treatment and preserve the peritoneal dialysis technique. In clinical practice, the first indication of peritonitis is often the appearance of cloudy dialysate, which is typically assessed visually and may therefore be subjective. Laboratory confirmation based on dialysate leukocyte count is commonly used but may delay early recognition of infection.

The objectives of this study are:
- To compare visual, physical, and laboratory diagnostic approaches and identify the earliest detectable markers of peritoneal dialysis-associated peritonitis.
- To develop a simulated model of peritoneal dialysis-associated peritonitis that allows visual and physical assessment of dialysate cloudiness.
- To develop machine learning and computer vision models for the early detection of peritoneal dialysis-associated peritonitis using clinical, biochemical, and visual data.
- To explore the potential role of bacteriophages as diagnostic and therapeutic tools in simulated peritoneal dialysis models.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/07/2025, Riga Stradiņš University Ethics Committee (Dzirciema street 16, Riga, 1007, Latvia; +371 67062617; pek@rsu.lv), ref: 2-PĒK-4/845/2025

Primary study design
Observational

Secondary study design
Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied
Early diagnosis of peritonitis in patients treated with peritoneal dialysis.

Interventions
This is a prospective observational single-centre study conducted at the Nephrology Centre of Pauls Stradiņš Clinical University Hospital (PSCUH), Latvia. Adult patients (≥18 years) receiving peritoneal dialysis will be included. Dialysate samples from patients with suspected or confirmed

peritoneal dialysis-associated peritonitis will be analysed using visual, physical, biochemical, and microbiological methods.

Standard diagnostic methods, including dialysate leukocyte count and microbiological culture, will be used as reference methods. Additional analyses will include physical turbidity measurements (densitometry, turbidimetry, and spectrophotometry), biochemical marker analysis, and standardized photographic documentation of dialysate samples.

A control group of clinically stable peritoneal dialysis patients without signs of infection will also be included. Data obtained from clinical, laboratory, and image-based analyses will be integrated to develop and validate machine learning models for early detection of peritoneal dialysis-associated peritonitis.

Additionally, a simulated peritonitis model will be developed by mixing infected and sterile dialysate to generate standardized turbidity levels for calibration of visual and physical measurement methods. Exploratory experiments will also assess the potential role of bacteriophages as diagnostic and therapeutic tools in simulated peritoneal dialysis environments

Intervention Type
Other

Primary outcome(s)
1. Diagnostic accuracy of the multimodal machine learning–based diagnostic algorithm for peritoneal dialysis-associated peritonitis measured using sensitivity and specificity of the algorithm compared with the current diagnostic standard of dialysate leukocyte count and clinical assessment at the time of suspected peritoneal dialysis-associated peritonitis

Key secondary outcome(s)
1. Changes in dialysis-effluent turbidity during the clinical course of PD-associated peritonitis measured using turbidimetry, spectrophotometry, and densitometry at presentation and during sequential follow-up sampling throughout treatment

2. Diagnostic performance of urine reagent strip testing for the detection of PD-associated peritonitis measured using urine reagent strip parameters, including leukocytes, protein, blood, and other available parameters, compared with conventional laboratory analysis at presentation and during follow-up sampling

3. Physical characteristics of experimentally simulated dialysis-effluent turbidity measured using turbidimetry, spectrophotometry, and densitometry at each predefined incremental turbidity level during experimental simulation

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Patients aged 18 years or older receiving peritoneal dialysis
2. Patients treated at the Nephrology Centre of Pauls Stradiņš Clinical University Hospital
3.Patients with clinically suspected or confirmed peritonitis
4. Availability of peritoneal dialysate samples for analysis

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients younger than 18 years of age
2. Patients not receiving peritoneal dialysis
3.Incomplete clinical, laboratory, or sample-related data preventing assessment of study outcomes
4. Samples not collected in accordance with the study protocol

Date of first enrolment
01/01/2026

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Latvia

Study participating centre
Rīga Stradiņš University, Department of Biology and Microbiology
Dzirciema street 16
Rīga
Latvia
1007

Study participating centre
Nephrology Center, Pauls Stradins Clinical University Hospital
Pilsoņu street 13, Riga, LV-1002, Latvia

Rīga
Latvia
1002

Sponsor information

Organisation
Riga Stradiņš University

Organisation
Pauls Stradiņš Clinical University Hospital

Funder(s)

Funder type

Funder Name
Latvijas Zinātnes Padome

Alternative Name(s)
Latvian Council of Science

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Latvia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Latvian		03/08/2026	No	Yes
Protocol file	in Latvian		03/08/2026	No	No