

Hospitalization in dialysis care

Submission date 30/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/03/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/04/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

End Stage Renal Disease (ESRD) occurs when the kidneys are no longer able to work at a level needed for day-to-day life. It is a chronic and complex disease. Patients with ESRD are treated with dialysis to replace kidney function at least three times per week. Hospitalization due to worsening of symptoms, and complications due to the underlying disease, is frequent. Assessing the risk of hospitalization and taking preventive actions would save the patient from unnecessary suffering. It would also be greatly beneficial from a healthcare economical perspective. LYRICS VÖR is an AI-driven monitoring system that flags patients at risk of hospitalization. It makes predictions based on physiological data, i.e. data captured by the dialysis equipment and assessments made at the dialysis clinic. The aim of this study is to assess whether patient-reported outcomes concerning wellbeing and symptoms improves the accuracy of predictions calculated in LYRICS VÖR.

Who can participate?

Patients aged 18 and over undergoing dialysis

What does the study involve?

Participants answer questionnaires at their regular dialysis treatments, ranging from 3-7 times per week. The questionnaires are completed on a tablet and the estimated time for each session is an average of 3-5 minutes.

What are the possible benefits and risks of participating?

Participants do not benefit from participation and there is no obvious risk associated with participation in the study.

Where is the study run from?

Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?

August 2017 to March 2019

Who is funding the study?

Lytics Health AB (Sweden)

Who is the main contact?
Assoc. Prof. Mikael Larson
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Contact information

Type(s)
Public

Contact name
Mr Mikael Larson

Contact details
Stortorget 13B
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Additional identifiers

Protocol serial number
VALA001

Study information

Scientific Title
Hospitalization in dialysis care - Investigation of predictive clinical methodology in renal disease and dialysis addressing risk for hospitalization

Acronym
VALA

Study objectives
The need to early identify subjects at risk is a critical success factor for treatment outcomes. Lytics has developed methodology, technology and tools for improved patient monitoring in collaboration with Centers for Dialysis Care, Inc. in Ohio, USA. The result of the collaboration, LYTICS VÖR, is an AI driven monitoring system that provides a comprehensive overview of extensive groups and flags patients at risk of hospitalization. LYTICS VÖR makes predictions based on physiological data, i.e data captured by the dialysis equipment and assessments made at the dialysis clinic. This study is designed to assess whether patient reported outcomes concerning subjective wellbeing and symptoms improves the accuracy of predictions calculated in LYTICS VÖR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala Etikprövningsnämnden (Regional Ethical Review Board), 10/01/2018, ref: 2018/870

Study design

Longitudinal open observational single-center study using an adaptive design

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

End Stage Renal Disease requiring hemodialysis

Interventions

After a patient is enrolled, an account will be set up in an anonymized web portal, and the patient is given a three digit enrollment number and chooses a four digit PIN-code that is used for logging into the web portal. They will be trained on a dummy version of the web portal prior to first login to the live system. At first login the patient will answer two questionnaires, first the KDQOL(TM)-36 (Kidney Disease Quality of Life - short form 36). The second questionnaire is not a validated questionnaire but rather questions based on the theories of Ed Diener concerning different dimensions of subjective wellbeing, henceforth addressed as the 'daily questionnaire'. On the second visit, which occurs on their next regular dialysis treatment, there will also be two questionnaires, an open source version of the Myers Briggs Type Index called 'Open Extended Jungian Type Scales 1.2' and the daily questionnaire. At each future dialysis treatment, the participant answers the daily questionnaire and once monthly they also answer the KDQOL(TM)-36. A patient will be enrolled in the study for a time period ranging from 3 to 10 months.

The primary outcome of the study is to assess if data on quality of life and subjective wellbeing can be used in predictive data analysis aimed at predicting future hospitalizations. The techniques used in analysis is an ensemble of different artificial intelligence algorithms. The predictions will be evaluated with AUC-ROC and Precision@k.

Intervention Type

Device

Primary outcome(s)

1. Quality of life, measured using the KDQOL(TM)-36 (Kidney Disease Quality of Life - short form 36) once monthly
2. Subjective wellbeing, measured using daily questionnaire at each dialysis treatment

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/2019

Eligibility

Key inclusion criteria

1. Provision of informed consent prior to any study specific procedures
2. Female or male 18 years of age or older

3. Subjects in dialysis care or subjects in potential of renal dialysis
4. Subject must be able to read and understand informed consent and questionnaires in the provided languages

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

The investigator will individually judge criteria for exclusion of any patient

Date of first enrolment

05/02/2018

Date of final enrolment

31/03/2019

Locations**Countries of recruitment**

Sweden

Study participating centre

Skåne University Hospital

Lund

Sweden

22185

Study participating centre

Skåne University Hospital

Malmö

Sweden

22185

Sponsor information

Organisation

Lytics Health AB

Funder(s)

Funder type

Industry

Funder Name

Lytics Health AB

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes