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Hospitalization in dialysis care

Submission date	Recruitment status	[_] Prospectively registered
30/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2019	Urological and Genital Diseases	[_] 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. LYTICS 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 LYTICS 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

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

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 measure

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

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

Sponsor details
Stortorget 13B
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21122

Sponsor type
Industry

Website
www.lytics.ai

Funder(s)

Funder type
Industry

Funder Name
Lytics Health AB

Results and Publications

Publication and dissemination plan
Study protocol will be published online at a later date. Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2020

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