

Validation of an instrument for measuring satisfaction of patients undergoing hemodialysis

Submission date 02/03/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/04/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/11/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hemodialysis (commonly known as kidney dialysis) is a way to remove waste from the blood when the kidneys are unable to do it on their own. This involves having the blood in the body be passed through a tube to a machine that is able to filter the waste. The blood is then passed back to the patient through another tube. This is usually done around four times a week and takes around four hours each session. As patients spend a long time in dialysis, it is important that patients are happy with their healthcare. Patients' satisfaction can be an indicator of the quality of healthcare services. Measuring patient satisfaction involves developing and validating a complex instrument. The Scale for Evaluation of Hemodialysis Patient's Satisfaction with Service (ESUR-HD scale) was developed by nurses and nephrologist (kidney doctors) in four different regions of Colombia that looked at satisfaction with service, personnel, medication and supplies, facilities and processes and phone contact. The aim of this study is to develop and validate ESUR-HD scale provided at a chronic kidney disease unit to see how well it can measure patient's satisfaction with their care.

Who can participate?

Adults over the age of 19 undergoing hemodialysis

What does the study involve?

Participants who underwent hemodialysis are contacted by telephone and are asked questions about their care using the ESUR-HD scale. The ESUR-HD scale uses 44 items that are rated from one to five. Some participants are also evaluated using the SDIALOR scale (another scale for measuring patient satisfaction). These scores are compared. A group of participants are also re-surveyed two days after their first survey to see if the test is reliable. Some participants are re-surveyed one month after they have hemodialysis in a newer clinic with newer equipment, waiting rooms, spaces and expert staff to see if the scale is sensitive to change.

What are the possible benefits and risks of participating?

There are no notable benefits or risks with participating.

Where is the study run from?
Renal Therapy Services (RTS) (Colombia)

When is the study starting and how long is it expected to run for?
January 2013 to December 2013

Who is funding the study?
Renal Therapy Services (RTS) (Colombia)

Who is the main contact?
Dr Mauricio Sanabria
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BHSR-D-16-00174

Study information

Scientific Title
Validation of an Instrument for Measuring Satisfaction of Patients Undergoing Hemodialysis:
ESUR-HD

Acronym

ESUR - HD

Study objectives

The aim of this study is to evaluate the psychometric properties of the Scale for Evaluation of Hemodialysis Patients' Satisfaction with Service (Spanish acronym ESUR) when applied to patients with chronic renal disease receiving hemodialysis treatment in renal care units in Colombia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Renal Therapy Services Colombia Ethics Committee, 11/06/2013, ref: minutes 004

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Haemodialysis

Interventions

After conducting four focus groups that include three nurses, a nephrologist and two administrative employees in four different regions of Colombia that asked about patient satisfaction, a scale for evaluating patients' satisfaction with the renal services ESUR-HD was created. The focus group defined certain dimensions with patient satisfaction that include overall satisfaction with the services, personnel at the unit, medications and supplies, facilities and processes, and phone contact. The ESUR-HD scale uses 44 items that are rated from one to five using a Likert scale. The final score is obtained by non-weighted sum of the score given to each item (higher scores reflect increased patient satisfaction). The survey takes 15 minutes to complete.

Participants who underwent hemodialysis at the clinics in 2013 are contacted by telephone to participate in the ESUR-HD scale. In order to measure convergent validity, the SDIALOR scale is simultaneously applied in a smaller subgroup of patients. The SDIALOR scale consists of seven

domains (organisation of medical care, relationship between nephrologists and general practitioner, locational characteristics, accessibility, care provided by the health personnel, information provided by the doctor, problem solving, overall satisfaction). In order to test the reliability of the study a smaller sample of participants were re-surveyed two days after their initial assessment to consider the scale length. In order to establish the sensitivity to change, another smaller sample of participants are re-evaluated one month after using a new renal clinical within a hospital that includes remodelled spaces, waiting rooms, newer equipment, with more familiar, expert and dedicated healthcare staff.

Intervention Type

Other

Primary outcome measure

1. Convergent validity is assessed by comparing the correlation coefficients based on results of ESUR-HD and SDIALOR at baseline.
2. Test-retest reliability is measured using repeat surveys of ESUR-HD at baseline and day 2.
3. Sensitivity to change is assessed by comparing the ESUR- HD scale scores at baseline and one month after improved care conditions

Secondary outcome measures

No secondary outcome measures.

Overall study start date

01/01/2013

Completion date

01/12/2013

Eligibility**Key inclusion criteria**

1. Adult patient undergoing hemodialysis
2. Colombian nationals
3. Speak Spanish
4. Aged 18 and older

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

370

Total final enrolment

370

Key exclusion criteria

1. Cognitive impairment, documented in the institutional clinical history, that prevents an adequate understanding of the questions contained in the instrument.
2. Sensory alterations, documented in the institutional clinical history, that prevent the patient from hearing the questions asked or responding to them in a telephone survey.

Date of first enrolment

01/06/2013

Date of final enrolment

01/09/2013

Locations**Countries of recruitment**

Colombia

Study participating centre

Renal Therapy Services (RTS) Colombia

Transv 23 # 97-73

Sixth Floor

Bogotá

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Sponsor information**Organisation**

Renal Therapy Services (RTS) Colombia

Sponsor details

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Sponsor type

Other

ROR

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Renal Therapy Services (RTS) Colombia

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mauricio Sanabria: mauricio_sanabria@baxter.com.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/05/2017	26/11/2020	Yes	No