ISRCTN63527489 https://doi.org/10.1186/ISRCTN63527489

Validation of the UDI- and IIQ-7 questionnaire in Lingala and Kikongo in an obstetric fistula population

Submission date	Recruitment status	[_] Prospectively registered
07/11/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/12/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2016	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstetric fistula is a hole in the birth canal caused by prolonged and obstructed labour. If left untreated in a patient, this leads to incontinence (constant and uncontrollable leakage of urine or faeces). When obstetric fistula (OF) repair takes place, the results are usually assessed by the surgical team and the patient perspective is often neglected. Urogenital distress inventory (UDI-6) and the impact of incontinence questionnaire (IIQ-7) are two internationally-validated questionnaires.
The aim of this study is to translate them in two Congolese local languages (Lingala and Kikongo) and to check whether that they can be used to assess the symptoms and the impact of urinary incontinence on the quality of life in patients with obstetric fistula.

Who can participate?
Female adults with fistula due to obstetric complications and able to fill in questionnaires

What does the study involve?
Answering questionnaires

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Saint Luc Hospital, Kisantu, Democratic Republic of Congo

When is the study starting and how long is it expected to run for?
October 2013 to January 2017

Who is funding the study?
Investigator led and funded. Incidental costs paid by Department of Urology, University Hospitals KU Leuven, Leuven, Belgium.

Who is the main contact?
Professor Dirk De Ridder
dirk.deridder@uzleuven.be

Contact information

Type(s)
Scientific

Contact name
Prof Dirk De Ridder

ORCID ID
http://orcid.org/0000-0001-6914-0077

Contact details
Urology
University Hospitals KU Leuven
Herestraat 49
Leuven
Belgium
3000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UDIIIQ-1

Study information

Scientific Title
Validation of the UDI- and IIQ-7 questionnaire in Lingala and Kikongo in an obstetric fistula population - an observational study

Study objectives
Urogenital distress inventory (UDI-6) and the impact of incontinence questionnaire (IIQ-7) are two internationally validated questionnaires on incontinence. It is hypothesised that these questionnaires can be translated and validated in two Congolese local languages (Lingala and Kikongo) and that they can be used to assess the symptoms and the impact on the quality of life of urinary incontinence in patients with obstetric vesicovaginal fistula.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Internal Review Board of the Hospital St. Luc, Kisantu, RD Congo

Study design
Observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Vesicovaginal fistula due to obstetric complications in a rural hospital in DR Congo

Interventions
Questionnaires, according to following methodologies.
- UDI-6 and IIQ-7 translated and undergoing content validity checks using focus groups.
- Final versions tested in a normal population and in an obstetric fistula population for internal consistency and test-retest reliability.
- Responsiveness tested in an obstetric fistula population and effect sizes calculated.

Intervention Type
Other

Primary outcome measure
Validation parameters: Crohnbach alpha, reliability, responsiveness

Secondary outcome measures
1. Fistula closure rate - number of healed fistula vs the number of persistent fistula after fistula surgery. This is assessed by clinical examination after 3 weeks.
2. Incontinence rate - number of patients with urinary incontinence (stress and/or urgency incontinence) while the fistula is healed. This is assessed by clinical examination at 3 weeks and 3 months after surgery.

Overall study start date
01/10/2013

Completion date
01/01/2017

Eligibility

Key inclusion criteria
Female patient with a vesicovaginal fistula due to obstetric complications.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Male
2. Unable to fill in a questionnaire
3. Fistula not due to obstetric complications

Date of first enrolment
01/10/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Congo, Democratic Republic

Study participating centre
Hôpital St. Luc
Kisantu
Inkisi
Province du Bas-Congo
Kisantu
Congo, Democratic Republic
NA

Sponsor information

Organisation

KU Leuven - dept. of urology

Sponsor details
Herestraat 49
3000
Belgium
3000

Sponsor type
University/education

ROR
https://ror.org/05f950310

Funder(s)

Funder type
University/education

Funder Name
Investigator initiated and self funded

Results and Publications

Publication and dissemination plan
Publication will be submitted to Neurourology and Urodynamics journal.

Intention to publish date
02/02/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from dirk.deridder@uzleuven.be.

IPD sharing plan summary
Available on request