

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

Submission date 07/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/12/2016	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

Validation parameters: Crohnbach alpha, reliability, responsiveness

Key secondary outcome(s)

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.

Completion date

01/01/2017

Eligibility**Key inclusion criteria**

Female patient with a vesicovaginal fistula due to obstetric complications.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

ROR

<https://ror.org/05f950310>

Funder(s)

Funder type

University/education

Funder Name

Investigator initiated and self funded

Results and Publications

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

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