

# Economic evaluation of Prostatic Urethral Lift (Urolift) (ECOLIFT)

**First published:** 20/02/2020

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Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/43662>

### EU PAS number

EUPAS33766

### Study ID

43662

### DARWIN EU® study

No

### Study countries

France

### Study description

Transurethral surgery such as transurethral resection of the prostate (TURP), laser enucleation or laser vaporisation, is the first line surgical treatment for bladder outlet obstruction secondary to benign prostatic hyperplasia. Even if bipolar and laser surgery have improved surgical outcomes in terms of length of hospital stay and post-operative complications, these procedures remain associated with a significant amount of infectious and bleeding complications, as well as with some persistent side effects such as sexual dysfunction and urinary incontinence. Prostatic urethral lift (Urolift) has been developed as a minimally invasive alternative to TURP with no need of general anaesthesia, less need of urinary catheter and less exposure to post-operative complication. Its efficacy and safety have been assessed by 2 clinical randomized trials with evidence of urinary symptom

improvement remaining inferior to TURP but durable for 5 years. Urolift preserved overall quality of life better than TURP. Urolift has been recommended by the EAU guidelines and recognized by French authorities but cannot be financed by the hospital itself. Reimbursement of the implants by healthcare system is therefore needed for the distribution of Urolift in France. The additional cost of the implants could be compensated by a reduced length of hospital stay and a lower rate of post-operative complications inducing healthcare expenditures. This study aims to assess if Urolift could be a cost-effective therapeutic strategy compared to transurethral surgery with 2 phases design: a field study comparing patients treated with Urolift to those treated with TURP/laser during 1 year follow-up, and an additional study comparing healthcare consumptions during 3 years follow-up between each group using data of the French National Claims Database (SNDS database).

## Study status

Ongoing

## Research institution and networks

### Institutions

#### Bordeaux University Hospital (CHU de Bordeaux)

France

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01/02/2024

Institution

Hospital/Clinic/Other health care facility

#### Bordeaux PharmacoEpi, University of Bordeaux

France

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08/02/2023

Institution

Educational Institution

Hospital/Clinic/Other health care facility

Not-for-profit

ENCePP partner

University Hospital of Bordeaux Bordeaux, France, University Hospital of Lyon Lyon, France, University Hospital of Montpellier Montpellier, France, University Hospital of Lille Lille, France, Hôpital Cochin - APHP Paris, France, University Hospital of Tours Tours, France

## Contact details

### Study institution contact

Grégoire ROBERT

Study contact

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### Primary lead investigator

Grégoire ROBERT

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned:

15/02/2020

Actual:

04/02/2020

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### Study start date

Planned:

01/06/2020

Actual:

21/04/2021

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### Data analysis start date

Planned:

01/03/2022

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### Date of interim report, if expected

Planned:  
30/09/2024

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### **Date of final study report**

Planned:  
30/09/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

NEOTRACT, INC

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Not applicable

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**If 'other', further details on the scope of the study**

Economic evaluation

**Main study objective:**

The main objective is to assess the incremental cost-effectiveness ratio of prostatic urethral lift (Urolift) compared to transurethral surgery (TURP/laser) 4 months after initial hospitalization.

## Study drug and medical condition

### Medical condition to be studied

Benign prostatic hyperplasia

## Population studied

### Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### Estimated number of subjects

1360

## Study design details

### Outcomes

Incremental cost per avoided complication (based on Clavien Dindo classification) of Urolift compared with classic transurethral surgery (TURP/laser) 4 months after the surgical procedure. Incremental cost/QALY of Urolift compared to transurethral surgery(1year). Real cost of hospitalization for each surgery. Healthcare consumptions(4,12,36months). Benign prostatic hyperplasia retreatment(12,36months). Urinary symptoms, sexual side effects, quality of life(4,12months). Time to recovery/return to professional activity(1,2,3,4months). Complications associated with surgery(4months).

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### Data analysis plan

SNDS patients will be matched to Urolift patients using a high dimensional disease risk score (hDRS) based on the 1-year SNDS information before surgery. Analyses will be done for each cohort according to matched treatment group: Description of populations - Comparison of baseline characteristics between Urolift and TURP/Laser cohorts and between Urolift and SNDS cohorts (before/after hDRS matching) - Estimation of cost-effectiveness ratios between Urolift and TURP/Laser cohorts (4 months,1 year) - Estimation of hospitalization cost for each surgery during hospital stay - Description of healthcare consumptions, disease retreatments, urinary symptoms, quality of life, time to recovery/return to professional activity, sexual side effects, associated complications - Comparison between Urolift and TURP/Laser cohorts and between Urolift and SNDS cohorts at 1, 3 years (intention-to-treat analysis using linear regression model and logistic

regression model adjusted on potential confounding).

## Data management

### Data sources

#### Data sources (types)

Administrative data (e.g. claims)

Other

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#### Data sources (types), other

Prospective patient-based data collection

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

#### Check conformance

Unknown

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#### Check completeness

Unknown

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#### Check stability

Unknown

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#### Check logical consistency

Unknown

### Data characterisation

#### Data characterisation conducted

No