

# The Uphold study

## Clinical evaluation of the Uphold Mesh for the surgical treatment of uterine-predominant prolapse: a prospective , multi-center trial

Published: 27-11-2012

Last updated: 26-04-2024

To evaluate the clinical efficacy after 12 months using a composite outcome: absence of apical prolapse (st 0 or I), absence of bulge symptoms, and absence of reintervention in the treated vaginal compartments (apical and anterior)

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

### Summary

#### ID

NL-OMON36892

#### Source

ToetsingOnline

#### Brief title

Uphold Study

#### Condition

- Other condition
- Uterine, pelvic and broad ligament disorders

#### Synonym

pelvic organ prolapse

#### Health condition

prolaps behandeling met toekomstig oog op vermindering van recidieven

## Research involving

Human

## Sponsors and support

**Primary sponsor:** CHU de Nimes, France

**Source(s) of monetary or material Support:** Boston Scientific via Universiteit van Nimes;Frankrijk

## Intervention

**Keyword:** Mesh, Pelvic organ prolapse, transvaginal, uterine

## Outcome measures

### Primary outcome

see above: composite outcome

### Secondary outcome

quality of life and bother scores and sexual function, measured with PFDI-20,

PFIQ-7 and PISQ-12.

## Study description

### Background summary

Prolapse repair using native tissue knows high recurrence rates. Mesh reinforced repairs reduce anatomic recurrence rates. Apical support is of crucial importance in prolapse repair surgery. Uphold Lite Mesh is CE marked and in use.

### Study objective

To evaluate the clinical efficacy after 12 months using a composite outcome: absence of apical prolapse (st 0 or I), absence of bulge symptoms, and absence of reintervention in the treated vaginal compartments (apical and anterior)

### Study design

prospective observational cohort, european multicenter

## Study burden and risks

as in routine vaginal prolapse repair surgeries

## Contacts

### Public

CHU de Nimes, France

Place du Professeur Debre 30029  
Nimes, France 30029 Cedex 09  
FR

### Scientific

CHU de Nimes, France

Place du Professeur Debre 30029  
Nimes, France 30029 Cedex 09  
FR

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

stage II or greater uterine and anterior vaginal wall prolapse

### Exclusion criteria

under age 50

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 20

Type: Anticipated

## Ethics review

Not approved

Date: 27-11-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

**In other registers**

<b>Register</b>	<b>ID</b>
Other	2011-A01705-36
CCMO	NL41643.098.12