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 evelauate 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)

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	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

Prolpapse 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 evelauate 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

Register	ID
Other	2011-A01705-36
CCMO	NL41643.098.12