

# The effect of a medical grade Honey formulation (L-Mesitran®) on vaginal Ulceration due to Pessary use: a feasibility pilot study

Published: 02-05-2024

Last updated: 18-01-2025

Objective: The primary objective is to investigate the effect on vaginal mucosa damage after the application of a Medical GradeHoney formulation (L-Mesitran ®) six weeks after starting treatment in patients with pelvic organ prolapse and pessary...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON57231

### Source

ToetsingOnline

### Brief title

The HUP trial

### Condition

- Other condition

### Synonym

pressure ulcers, vaginal ulceration

### Health condition

vaginaal epitheel/mucosa

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum

**Source(s) of monetary or material Support:** Geen geldstroom. Enkel levering van de bacteriele kweken en medicinale honing door Triticum BV (L-Mesitran). ,Triticum Exploitatie BV

## Intervention

**Keyword:** medical grade honey, Pelvic organ prolaps, pessary therapy, vaginal ulceration

## Outcome measures

### Primary outcome

The primary objective is to investigate the effect on vaginal mucosa damage after the application of a Medical Grade Honeyformulation (L-Mesitran ®) six weeks after starting treatment in patients with pelvic organ prolapse and pessary treatment.

The vaginal mucosa damage is categorized in yes or no, and a more differentiated scoring of the stage of disturbance, using a modification of the staging I-IV of Campbell (the decubitus ulcer).

### Secondary outcome

Secondary objectives are to investigate the effect on complaints (vaginal bleeding, vaginal discharge, pain, odor, discomfort and pHmucosa with an additional microbiological swab test result). Moreover, information about side effect, discomfort and patient globalimpression of improvement will be collected and compared.

# Study description

## Background summary

Rationale: In accordance with current guideline nearly 98% of urogynecologists prescribe pessary among patients with pelvic organ prolapse (POP), to provide anatomic support and as a treatment of choice or in those who decline surgery. Localized pressure effect, and vaginal epithelium architecture changes, can result in ulceration and abrasions of the vaginal mucosa, with a wide variety among the different shapes and sizes of the pessary. Rates vary in the literature among 3 to 24%. It is possible that atrophy and/or the presence of bacterial vaginosis (BV) contribute to the development of pressure ulcers. Currently, the majority of urogynecologists recommend concurrent vaginal estrogen therapy with pessary use to limit complications, to treat or prevent decubitus ulcer; however limited data exists to support this daily recommended practice. An alternative therapy is not yet known. Recent literature show that medical grade honey (MGH) has protective, antimicrobial and immunomodulatory activity and may therefore be a good alternative treatment. A parallel can possibly be drawn to the treatment of diabetic (foot) pressure ulcers with medicinal honey. The application of MGH effectively enhanced wound repair. We believe that MGH will modulate the vaginal microenvironment by its anti-inflammatory, anti-oxidative and immunomodulatory properties, and subsequently may decrease the presence and vaginal ulceration when compared to estrogen.

## Study objective

Objective: The primary objective is to investigate the effect on vaginal mucosa damage after the application of a Medical Grade Honey formulation (L-Mesitran®) six weeks after starting treatment in patients with pelvic organ prolapse and pessary treatment.

The vaginal mucosa damage is categorized in yes or no, and a more differentiated scoring of the stage of disturbance, using a modification of the staging I-IV of Campbell (the decubitus ulcer).

Secondary objectives are to investigate the effect on complaints (vaginal bleeding, vaginal discharge, pain, odor, discomfort and pH mucosa). Moreover, information about side effect, discomfort and patient global impression of improvement will be collected and compared.

## Study design

Study design: feasibility pilot study

## Intervention

Intervention 1: Estrogen (Synapause-E3®). Therapy according manufacturer\*s instructions. As treatment for vaginal ulceration: single daily vaginal insertion (1 ovule of 0.5mg) during the first two weeks, after these first two weeks single vaginal insertion (1 ovule of 0.5mg) a day two times a week for a total period of six weeks.

Intervention 2: Medical Grade Honey Formulation (L-Mesitran®)

As treatment for vaginal ulceration - Single daily application (5 grams with applicator) during the first two weeks, after these first two weeks single vaginal application (5 grams with applicator) ) a day two times a week for a total period of six weeks.

### **Study burden and risks**

No difference between current standard treatment

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

**Inclusion criteria**

Postmenopausal patients with a pessary because of pelvic organ prolapse or incontinence with clinical signs of vaginal ulceration.

- Women with a pessary because of pelvic organ prolapse or incontinence
- postmenopausal (last menstrual bleeding one year ago)
- Clinical diagnosis of at least symptoms correlated with vaginal epithelium architecture changes, signs of atrophy and/or vaginal ulceration.
- Capacity to understand, consent, and comply with the trial procedures

**Exclusion criteria**

- Women who are premenopausal
- Women using vaginal medication during the last three months prior to inclusion
- Women using immunosuppressants
- Women with a history of vasculitis and/or diabetes mellitus
- Known allergies or contra-indications for honey or estrogen

**Study design**

**Design**

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

**Recruitment**

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	32

Type: Anticipated

## Medical products/devices used

Generic name: L-Mesitran

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 02-05-2024

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

## 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
CCMO	NL86076.096.24