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...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	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 organprolapse (POP), to provide anatomic support and as a treatment of choice or in those who decline surgery. Localized pressureeffect, and vaginal epithelium architecture changes, can result in ulceration and abrasions of the vaginal mucosa, with a wide varietyamong the different shapes and sizes of the pessary. Rates vary in the literature among 3 to 24%. It is possible that atrophy and/orthe presence of bacterial vaginosis (BV) contribute to the development of pressure ulcers. Currently, the majority ofurogynecologists recommend concurrent vaginal estrogen therapy with pessary use to limit complications, to treat or preventdecubitus 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 maytherefore be a good alternative treatment. A parallel can possibly be drawn to the treatment of diabetic (foot) pressure ulcers withmedicinal honey. The application of MGH effectively enhanced wound repair. We believe that MGH will modulate the vaginalmicroenvironment by its anti-inflammatory, anti-oxidative and immunomodulatory properties, and subsequently may decrease thepresence 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 GradeHoney 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 pHmucosa). Moreover, information about side effect, discomfort and patient global impression of improvement will be collected andcompared.

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
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419PC
NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419PC
NL

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