Acceptance and ease of use of the vaginal Dummy MedRing by female volunteers

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55039

Source
ToetsingOnline

Brief title
MedRing-01

Condition

- Other condition

Synonym
but the condition (OAB) will not be examinated, patients with over active bladder are participants in the study as well as patients without over active bladder

Health condition

geen, hulpmiddel is dummy

Research involving
Human

Sponsors and support

Primary sponsor: LiGalli BV
Source(s) of monetary or material Support: LiGalli BV;Den Haag

Intervention

Keyword: Dummy, over active bladder, Vaginal ring

Outcome measures

Primary outcome

7.1 Primary objective

The primary objective of the study is to assess the attitude towards the use of

the MedRing

Secondary outcome

7.2 Secondary objective

The secondary objectives of the study are to assess device related adverse

events, device damage and physician satisfaction.

Study description

Background summary

Vaginal rings, also called pessaries, are being used for many decades in gynaecological practice. A wide variety of rings has been used and are still used for urogenital problems as urinary incontinence. The safety of use of vaginal rings has been well established. [REF-1]
Pessaries are used for urinary incontinence and pelvic organ prolapse (POP). These indications are all relatively long-term indications and often require long-term use of the product. Most intravaginal pessaries are currently manufactured from medical grade silicone because the material is flexible, pliable, long-lasting, non-absorbent, biologically inert, non-allergenic, non-carcinogenic, washable and can generally be sterilized using boiling water. [REF-2]
The Sponsor, LiGalli, is developing MedRings for vaginal drug delivery and/or diagnostics. The heart of this device in development is a micronized

electromechanical system. Vaginal drug delivery and body signal registration offers many advantages. The first intended application of the MedRing is the vaginal programmed administration of oxybutynin for female patients suffering from overactive bladder syndrome (OAB). OAB is defined as *urinary urgency, usually with urinary frequency and nocturia, with or without urgency urinary incontinence* according to the guidelines of the ICS/IUGA. [REF-3,4]
The current routes of administration of oxybutynin are being accompanied with frequent and severe side effects. Up to 60% of the users experience anticholinergic side effects of the oral route medication. The transdermal route with the use of a oxybutynin patch suffers from skin irritation causing cessation of the therapy by a high number of users. Side effects cause withdrawal from treatment with both treatment routes.
Controlled vaginal administration of oxybutynin could have the potential to be effective at low dose with minimal anticholinergic side effects.
The vaginal route of drug delivery can be typified as a *semi-parenteral* route and the uptake of medication(s) by the vaginal mucosa is excellent. Direct action at target, no first-pass via the liver as in gastro-intestinal uptake.
In addition, compounds with a low bioavailability or high first-pass effect in chronic diseases are well suited for this route of drug delivery.
The vaginal mucosa has proven to be an excellent place for diagnostics, due to the close vicinity of dense vascularization. Recently, a high accuracy in detecting various chemical compounds and hormones was found.
The electromechanical nature of the future product makes it *smart* and provides flexibility in dosage, schedule and timing. The future device can be wirelessly adjusted and controlled.
Although the use of vaginal rings is well accepted, Ligalli wants to have an acceptability study done to be well informed about the acceptance of the device by users on ease of use, comfort of use, adverse effects and willingness to use a vaginal MedRing for therapeutic or diagnostic purpose. The acceptability study will be executed with a Dummy MedRing from equal medical grade material and consistency as the future MedRing for drug delivery or diagnostic body signals registration. The Dummy MedRing does not contain functional content (no software and no pharmaceutical ingredient).

Study objective

7.1 Primary objective
The primary objective of the study is to assess the attitude towards the use of the MedRing
7.2 Secondary objective
The secondary objectives of the study are to assess device related adverse events, device damage and physician satisfaction.

Study design

8 DESIGN OF THE CLINICAL STUDY

This is a prospective, open label, interventional, monocenter study to assess user acceptability of the Dummy MedRing. The expected enrolment period will be 2 months. The individual duration of the study for the subjects will be 1 month.
8.1 Study design
Subjects will be selected by the Investigator and asked for participation after oral and written information on the study in a screening visit (visit 1). If the subject accepts, a patient informed consent (PIC) form is handed over and a study visit will be scheduled.
At the next visit (enrolment, visit 2, Day 1) the informed consent form is signed. After enrolment and instructions, the subject will self-insert the ring and wear it for one hour within the clinic, then self-remove. The ring will be cleaned and re-inserted. This ring will be worn for one week and the subject will visit the clinic again (visit 3) and self-remove again. After examination and cleaning, the ring will be self-inserted the third time, worn for two weeks and self-removed at the final visit (visit 4). A telephone contact will take place a week later for safety follow-up. See Section 8.6 for details per visit.
Data will be collected using questionnaires for subjects and Investigator, and diaries for subjects.

Intervention

insertion of vaginal ring

Study burden and risks

There are no direct benefits for the subjects.

A risk assessment has been carried out and after risk controlling measures the residual risk associated to the manufacture and use of this product is low. After evaluating the severity and occurrence of the residual risks it is concluded that the overall residual risk level is acceptable. Furthermore, in-use studies have shown that the product can be inserted, worn, and removed as intended and no unforeseen risks have come forward.
There is a low risk on side effects like vaginal wall irritation, cramps, vaginal discharge or vaginal bleeding. As vaginal rings (pessaries) have been used for decades with a high safety profile and track record, the safety of use of the MedRing Dummy can be expected as high and acceptable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

8.4.1 Inclusion criteria
1. Subject is female.
2. Subject is willing and able to give written consent for study participation.
3. Subject is aged >=25 and <=75 years.
4. Use of adequate contraception method (if applicable).
5. Screening on cervical cancer less than 5 years ago with normal result.

Exclusion criteria

1. Pregnancy.
2. Irregular vaginal bleeding.
3. The subject has a history of vaginal surgery.
4. The subject has a clinical relevant genital prolaps (POP-Q stage 2).
5. Known hypersensitivity to device material (polypropylene, styrene triblock copolymer, parafin oil, glue, primer, coloring agents).
6. The subject has symptomatic vaginal discharge (e.g. with itching or bad odour).
7. Any current illness that would jeopardize the subject*s health or

interpretation of the results of the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	vaginal ring
Registration:	No

Ethics review

Approved WMO

Date:	14-05-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	17-11-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	23-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Not approved

Date:	22-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL73374.100.20