An open-label, two-way cross-over, randomized study to assess the pharmacokinetics and safety/tolerability of intra-vaginal delivery of gonadorelin and oxybutynin in healthy female volunteers

Published: 16-09-2015
Last updated: 19-04-2024

1. To explore the pharmacokinetics (PK) of intra-vaginal delivery of gonadorelin and oxybutynin. 2. To assess the safety and tolerability of gonadorelin and oxybutynin delivery with a prototype intra-vaginal ring.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON42626

Source
ToetsingOnline

Brief title
Pharmacokinetics of intravaginal drug delivery

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Bladder and bladder neck disorders (excl calculi)

Synonym
NA, pharmacokinetics of oxybutynin and gonadorelin

Research involving
Human

Sponsors and support

Primary sponsor: LiGalli BV
Source(s) of monetary or material Support: LiGalli B.V.

Intervention

Keyword: gonadorelin, intravaginal, oxybutynin, pharmacokinetics

Outcome measures

Primary outcome

PK parameters (Cmax, tmax, t1/2el, AUC) of oxybutynin and gonadorelin

Secondary outcome

Safety endpoint such as

((S)AEs).

Concomitant medication

Vital signs

Vaginal examination

Study description

Background summary

Controlled release technologies including sustained release of oral medication, implants and transdermal drug delivery have been developed to mimic physiological concentrations and endogenous substance profiles. However, there is still a need to develop novel technologies. The intra-vaginal delivery route may facilitate such novel technology as it offers several advantages for systemic drug delivery.
To date no intra-vaginal controlled drug delivery method is available. Therefore, a vaginal ring with a reservoir for pulsatile, continuous, or pre-programmed intra-vaginal drug delivery is being designed.

Study objective

1. To explore the pharmacokinetics (PK) of intra-vaginal delivery of gonadorelin and oxybutynin.
2. To assess the safety and tolerability of gonadorelin and oxybutynin delivery with a prototype intra-vaginal ring.

Study design

An open-label, two-way cross-over, randomized study

Intervention

Intravaginal administration of a single dose of oxybutynin (1 mg) and gonadoreline (1 mg) on 2 different occasions

Study burden and risks

Burden: oxybutynine/gonadorelin administration, blood sampling, compliance with lifestyle restrictions and time investment
Risk: potentials side effects of gonadorelin and oxybutynin and potential complaints caused by blood sample collection

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

1. Healthy female subjects aged between 18 and 40 years (inclusive)
2. Body mass index between 18-32 kg*m2 (inclusive);
3. Using oral contraceptives of second generation containing ethinylestradiol and progesterone derivate.

Exclusion criteria

1. Clinically significant abnormalities in laboratory test, vital signs and ECG
2. Being a virgin.
3. History of sexual abuse/violence.
4. Being pregnant or breast feeding

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	06-11-2015
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lutrelef
Generic name:	Gonadorelin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Oxybutynin Hydrochloride
Generic name:	Oxybutynin Hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	16-09-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-11-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2015-003725-34-NL
CCMO	NL54903.058.15