Pharmacokinetics of nitrofurantoin in the elderly

Published: 23-10-2013
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The primary objective of this study is to provide an updated pharmacokinetic profile of orally administered nitrofurantoin in women aged 55 to 75 years.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON38966

Source
ToetsingOnline

Brief title
Pharmacokinetics of nitrofurantoin

Condition

- Bacterial infectious disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym
cystitis, urinary tract infection (UTI)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: AIDA (FP7 project EU)

Intervention

Keyword: Elderly, Nitrofurantoin, Pharmacokinetics, Urinary tract infection

Outcome measures

Primary outcome

Concentration-time curve of nitrofurantoin

Secondary outcome

not applicable

Study description

Background summary

Nitrofurantoin is an antibiotic used for the treatment of lower urinary tract infections for more than 50 years. There has been a recent resurgence of interest in this drug in the context of increasing multidrug resistance amongst Gram-negative bacteria causing urinary tract infections. However, given the era of its development, there is a paucity of pharmacokinetic data for nitrofurantoin that meet contemporary standards.

Study objective

The primary objective of this study is to provide an updated pharmacokinetic profile of orally administered nitrofurantoin in women aged 55 to 75 years.

Study design

We propose a prospective study of nitrofurantoin*s pharmacokinetics in female patients. This study will involve patients after their physician prescribed nitrofurantoin for (suspected) urinary tract infection. After the start of therapy patients will be asked informed consent. Demographic and clinical data will be collected from patients in addition to blood and urine samples in order to perform population pharmacokinetic modelling to produce a full pharmacokinetic profile of nitrofurantoin in female patients with urinary tract infection.

Study burden and risks

intravenous catheter for 6 hours and collection of urine during 24 hours

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert grooteplein-zuid 10
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert grooteplein-zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- use of nitrofurantoin
- female sex

Exclusion criteria

- Treated with any antibiotics within 1 week of potential sampling period
- Known allergic reaction or anaphylactic shock as a result of the consumption of

nitrofurantoin

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	NITROFURANTOIN APOTEX MC 50 mg
Generic name:	Nitrofurantoin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-10-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-11-2013
Application type:	First submission

Review commission: METC Brabant (Tilburg)

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	EUCTR2013-004174-10-NL
CCMO	NL46061.008.13