Oseltamivir Pharmacokinetic Cohort Study

Published: 30-11-2009
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Primary: To determine the pharmacokinetics of oseltamivir in children and in adults with significant co-morbiditiesSecondary: To examine whether the pharmacokinetics in our studied populations are comparable with the PK in other populations To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON32852

Source
ToetsingOnline

Brief title
OPC study

Condition

- Viral infectious disorders

Synonym
flu, Influenza

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: NLADF

Intervention

Keyword: Adults with co-morbidities, Children, Oseltamivir, Pharmacokinetics

Outcome measures

Primary outcome

Pharmacokinetics

Secondary outcome

Adverse events

Oropharyngeal viral load

Study description

Background summary

Oseltamivir treatment is currently the preferable treatment option in patients infected with H1N1 influenza. Oseltamivir is an ester prodrug which is rapidly hydrolysed by liver carboxylesterase to the active metabolite oseltamivir carboxylate. Oseltamivir carboxylate is a selective neuramidase inhibitor of influenza A and B. Oseltamivir and its hydrolysed carboxylate are almost fully excreted renally by glomerular filtration and active tubular secretion. The pharmacokinetics of oseltamivir in adults has been determined in several studies. However, the pharmacokinetics in infected adults with significant co-morbidities has not been studied, while these patients have an increased risk for serious morbidity and even mortality when infected with influenza A or B. Also, limited data is available regarding the pharmacokinetics of oseltamivir in children and no data are available in children <3 months of age, while these patients also have an increased risk for serious consequences of an influenza infection. Currently, patients at risk are treated with oseltamivir, according to national guidelines, while knowledge of the pharmacokinetic properties of the drug is still limited.

Study objective

Primary:
To determine the pharmacokinetics of oseltamivir in children and in adults with significant co-morbidities

Secondary:

To examine whether the pharmacokinetics in our studied populations are comparable with the PK in other populations
To examine the relationship between treatment related adverse events and plasma drug levels and oropharyngeal viral load and plasma drug levels
To evaluate the specific influence of patient related parameters on pharmacokinetic variability

Study design

Prospective cohort study

Study burden and risks

The sampling scheme of the oseltamivir pharmacokinetic cohort study will be minimally invasive. If possible blood sampling will be carried out during routine laboratory testing and will not require additional vena punctures. However, in some cases this may be necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Child <13 years or adult with significant co-morbidities
- Oseltamivir treatment
- Hospitilisation

Exclusion criteria

- No written informed consent
- Unable to fulfil study procedures
- Difficult to obtain blood samples

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2009
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL30721.048.09