Immune respons after inactivated oral cholera vaccination (Dukoral) in kidneytransplant recipients. Mucosal immune response in ImmunoCompromised Host (MICH)

Published: 25-01-2010
Last updated: 30-04-2024

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

Summary

ID

NL-OMON35457

Source
ToetsingOnline

Brief title
MICH

Condition

- Gastrointestinal infections

Synonym
ETEC-diarrhoea, travelers diarrhoea

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cholera toxin B, Immunodeficiency, Renal transplant, Vaccine

Outcome measures

Primary outcome

-

Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Intervention

-

Study burden and risks

-

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >= 18 years
- Creatinin clearance >= 40 ml/min
- Stable renal function for 1 year prior to inclusion
- Stabe immunosuppressive medication for 3 months prior to inclusion, consisting of prednisone in combination with either a calcineurine inhibitor, mycophenolate mofetil or an mTOR inhibitor

Exclusion criteria

- A chronic disease which may influence the immune system, other than the renal transplant and accompanying immunosupressive medication
- Chronic infection
- Treatment for graft rejection in the year prior to inclusion
- Prior vaccination with Dukoral or another oral cholera or ETEC vaccine.
- Prior Vibrio cholerae infection

- Travellers' diarrhea 6 months prior to inclusion
- Known allergy to the vaccine or to one of the vaccine components
- History of an anaphylactic reaction following vaccination
- Treatment with plasma or blood products in the 3 months prior to inclusion
- Pregnancy or breast feeding
- Immunosuppressive medication other than prednisone, a calcineurine inhibitor, mycophenolate mofetil or an mTOR inhibitor

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2010
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	cholera vaccine (inactivated, oral)

Ethics review

Approved WMO

Date:	25-01-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	12-03-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2010-018377-38-NL
CCMO	NL28010.058.10